Hypnosis for Pain Management During Childbirth: A Meta-analysis

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Statement

I declare that this thesis is my own work and that, to the best of my knowledge and belief, it does not contain material from published sources without proper acknowledgement, nor does it contain material which has been accepted for the award of any other higher degree or graduate diploma in any university.

Signed .....

Date.....23/04/13.....

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Abstract

The objective of this study was to examine the effects of hypnosis for pain management during childbirth. Randomised controlled trials and quasi-randomised controlled trials comparing preparation for labour using hypnosis and/or use of hypnosis during labour, with placebo, no treatment or any analgesic drug or technique were eligible to be included in the analysis. Participants in the studies were pregnant women. A random effects model was used to analyse the data due to the high level of statistical heterogeneity between the trials. Seven trials randomising a total of 1213 women were included in the analysis. All but one of these trials were assessed to be at moderate to high risk of bias. One trial was assessed as being at low risk of bias across all domains. The results indicated that hypnosis did not have a significant effect on the use of pharmacological analgesia, including epidural, on mode of birth or on satisfaction with pain relief. There was a trend towards women in the hypnosis group being less likely to use pharmacological pain relief or analgesia than those in the control group, although the result did not reach statistical significance (p = 0.06, average risk ratio (RR) 0.63, 95% confidence interval (CI) 0.39, 1.01, 6 studies, 1032 women). However, there was statistically significant heterogeneity. Overall, there are still only a small number of studies assessing the use of hypnosis for labour and childbirth. Although the intervention shows some promise, further research is needed before recommendations can be made regarding its clinical usefulness for pain management in maternity care.

Hypnosis for Pain Management for Childbirth: A Meta-analysis

What is Labour Pain?

Labour pain has traditionally been defined similarly to acute pain, "a complex constellation of unpleasant sensory, perceptual and emotional experiences and certain associated autonomic, physiologic, emotional and behavioural responses" (Bonica, 1990, p. 19). However, unlike other acute pain, which can usually be attributed to pathologic processes, labour pain does not signal harm or pathology and is considered a normal part of birth (Lowe, 2002).

A major review by Lowe (2002) noted that women's experiences of pain during labour are complex phenomena and although almost all women report some pain during childbirth, their sensory and affective perceptions can vary widely. For example, some women describe the sensations of labour as more akin to extreme muscular exertion from physical activity, some as productive pain which signals that their baby's birth is closer, some compare it with intense period pain and others describe it as agony or like torture (Green, Coupland, & Kitzinger, 1998; Lundgren & Dahlberg, 1998; McCutcheon-Rosegg, Ingraham, & Bradley, 1996). There have also been reports that occasionally women experience no labour pain and give birth unexpectedly (Gaskin, 2003). This complexity has even been found to extend to individual women's descriptions and ratings of the sensations of labour (Green, et al., 1998; Lundgren & Dahlberg, 1998). One of the key themes identified by Lundgren and Dahlberg in a qualitative study of the experience of pain during childbirth was that the pain was hard to describe and contradictory. For example, one of the participants stated: "I think it's a happy pain, though it is a hell... that's what it is, and a little more ... but just that it... it's very hard to explain" (Lundgren & Dahlberg, 1998, p. 107).

In order to understand the nature of labour pain more clearly, the following sections will first consider the sensory and affective components of pain and then examine the physiological and psychological factors that have been found to be correlated with labour pain. A major section will follow focusing on the management of pain in childbirth. This section will initially review common methods of relieving pain in childbirth and examine where hypnosis sits within this context, both historically and in contemporary maternity care. Different methods for providing hypnosis for childbirth will be considered, together with analysis of the rationale and critiques for each method. Previous research into the effectiveness and safety of hypnosis for pain relief, including pain management for childbirth will be reviewed and critiqued. Finally the rationale and aims for the current study will be outlined.

Sensory and Affective Components of Pain

While there has traditionally been a distinction made between the sensory and affective components of pain it is only relatively recently that neurophysiological studies have provided evidence supporting the theory that separate neuronal pathways are involved (Rainville, Duncan, Price, Carrier, & Bushnell, 1997). The affective component of pain has been described as the emotional component of pain (Lowe, 2002) and includes elements such as perceived unpleasantness of a stimulus while the sensory dimensions of pain include elements such as the intensity, location and quality of the sensation (Melzack & Casey cited in Rainville et al., 1997). In a positron emission tomography (PET) study of human cortical activation, Rainville et al. selectively altered the degree of unpleasantness of a hot, noxious stimulus without changing the perceived intensity of the pain. They found that activation in the primary somatosensory cortex did not change when the degree of unpleasantness was altered but there were significant changes in the pain-evoked activity within the anterior cingulate

cortex. This study provided experimental evidence that distinct cortical areas are involved in the sensory and affective components of pain experiences.

The distinction between the affective and sensory components of pain has also been examined specifically in relation to labour pain. Price, Harkins and Baker (1987) had women rate their pain on both a visual analogue scale for pain sensation (VAS sensory) and a visual analogue scale for degree of unpleasantness (VAS affective) at four points during their labour. Overall, they found that women's ratings of sensory pain were significantly higher than their ratings of affective pain for all stages of labour except early labour (less than 4cm cervical dilation). In addition, they found that the women's affective, but not sensory ratings of pain were much lower when they reported that they were focused on the birth of their baby rather than on the pain sensations. The research also compared the women's pain ratings on both scales with patients who had chronic pain, cancer pain and healthy volunteers exposed to experimental pain. Only those in the experimental pain condition had a similar pattern to the labouring women in rating their affective pain lower than their sensory pain. Overall the chronic pain and cancer pain patients had significantly higher ratings of affective pain than sensory pain. They concluded that psychological contextual factors, such as perceived threat to health or life, had a major influence on the affective dimension of pain perception for different types of pain.

In a thoughtful exploration of the relationships between pain and suffering, Chapman and Gavrin (1993) noted that potentially painful and threatening situations can, under some circumstances, be experienced as challenging and exhilarating rather than as a cause of suffering. They proposed that individuals' experiences might depend on factors such as a sense of having sufficient resources to cope with the challenge. Lowe (2002) noted that this insight was particularly relevant to the experience of pain in childbirth and may help explain why psychosocial interventions such as having a

support person for labour and childbirth preparation could be helpful for women, even if they did not reduce the sensory component of pain. The relationships between several psychosocial and physiological factors and labour pain will be examined further in the following section.

Physiological and Psychological Correlates of Labour Pain

Physiological factors. The review by Lowe (2002) identified a range of physiological and psychosocial factors that are important in understanding the nature of labour pain. Bonica and McDonald (1990) noted that the physiological processes, which are thought to cause pain during labour, include uterine contractions dilating the cervix in the first stage of labour and the stretching of the vagina and pelvic floor as the baby descends during the second stage of labour. Although pain intensity has been found to increase with the frequency of uterine contractions and greater cervical dilatation, these patterns are not consistent across all women (Melzack, Kinch, Dobkin, Lebrun, & Taezner, 1984). Lowe reported that relationships have been demonstrated between women's pain experiences and a range of physical factors including parity and maternal positioning. For example, women in labour for the first time (nulliparas) have consistently been found to experience greater pain intensity than parous women in early labour (before the cervix is 5cm dilated). The current study will assess parity as a potential moderating variable.

Maternal positioning has also been found to effect women's experiences of labour pain and upright positions have been shown to have particular benefits (Gupta, Hofmeyr, & Smyth, 2004; Lawrence, Lewis, Hofmeyr, Dowswell, & Styles, 2009). Lawrence et al. found that women randomised to upright positions in the first stage of labour were less likely to use epidural analgesia than women randomised to recumbent positions (Risk Ratio (RR) 0.83, 95% Confidence Interval (CI) 0.72 to 0.96). Further, Gupta et al. showed that in the second stage of labour women in any upright or lateral

position were less likely to report severe pain than women lying on their back. Lowe (2002) noted that there has been mixed evidence about the relationship between fetal weight and maternal height/weight ratios and pain experience. Melzack et al. (1984) found that women with a greater weight to height ratio had higher pain scores than women with a lower weight to height ratio and that for women who had previously given birth, the infant's weight was also positively correlated with pain scores. However, these relationships were not replicated in later studies (for example, Lowe, 1991; Ranta, Jouppila, Spalding, & Jouppila, 1995). Lowe (2002) suggested that such a relationship may only have clinical relevance for very heavy babies and may also depend on relative size of the baby compared with the mother.

Psychosocial factors. A range of psychosocial factors including anxiety, fear, feelings of self-efficacy, coping skills, expectations and social support have also been shown to impact upon women's experiences of labour and labour pain (Hodnett, Gates, Hofmeyr, & Sakala, 2011; Lowe, 2002). Maternal anxiety has consistently been shown to be positively correlated with increased pain in labour (for example, Alves, Zakka, Teixeira, Siqueira, & Siqueira, 2008; Lowe, 1987). Lowe (1996) noted that although some anxiety is considered normal in labour, excessive anxiety leads to the release of additional stress hormones which can decrease blood flow to the pelvic area and increase muscular tension. Lowe proposed that these physiological changes and the emotional experience of heightened anxiety may amplify the pain stimuli from the pelvis and increase the cortical perception of pain. She also noted that anxiety about childbirth can include a range of concerns including fear of pain, loss of control and fears about the wellbeing of the baby and the mother.

Women's feelings of fear and anxiety were theorised by Dick-Read (1947) to be linked to muscular tension and pain in childbirth in a cyclical fear-tension-pain syndrome where high levels of fear increased muscular tension, causing increased pain

which in turn further heightened the woman's level of fear. This theory has been explicitly incorporated into a range of childbirth education programs such as Hypnobirthing: the Mongan Method and the Australian calmbirth program (Jackson, 2011; Mongan, 2005) and many antenatal education programs seek to reduce maternal anxiety and increase confidence.

A Cochrane Review has demonstrated that continuous social support during labour had a positive effect on women's satisfaction with their childbirth experience and reduced use of pharmacological analgesia (Hodnett et al., 2011). They identified the key elements of this support to include emotional support, information, suggestions of coping techniques, comfort and advocacy for the labouring woman. Hodnett et al. theorised that this type of support may enhance women's feelings of control and competence as well as promote normal labour physiology through reduced stress responses and the use of movement and positioning.

Management of Pain in Childbirth

Women use a wide range of methods for pain management during childbirth and major reviews have been completed for 14 pharmacological, physical and psychological interventions (recently combined into a Cochrane overview of systematic reviews by Jones et al., 2012). Common methods include pharmacological options such as epidural analgesia, opioids and inhaled analgesia as well as non-pharmacological methods such as water immersion, massage, movement and relaxation techniques. Evidence from the Jones et al. overview of systematic reviews suggests that while the pharmacological methods of epidural, combined spinal epidural and inhaled analgesia are effective in managing pain during childbirth they increase the risk of adverse effects. For example women who used epidural analgesia were more likely to have an instrumentally assisted birth, experience hypotension or fever (Jones et al., 2012). Jones et al. also found some evidence that non-pharmacological methods such as relaxation, acupuncture, water

immersion and massage may assist in managing labour pain with few adverse effects but this evidence was often based on single trials. It has been suggested that renewed interest in non-pharmacological methods of pain management reflects a range of factors including cultural changes in attitudes towards childbirth as well as concerns about the medicalization of birth and potential adverse effects from pharmacological analgesia (Caton, Frolich, & Euliano, 2002; Johanson, Newburn, & Macfarlane, 2002).

There is very limited data available on the acceptability of various methods of pain relief to pregnant women. One Australian study did find that 62% of women planned to use 'natural methods' as pain relief for labour, 37% planned to use nitrous oxide, 26% planned an epidural and 13% planned to use pethidine (Henry & Nand, 2004). However, a major limitation of this study was that women were asked to nominate their antenatal plans after their baby was born, potentially leading to recall bias, where actual events may influence what is recalled or recall may be inaccurate due the time delay (Henry & Nand). No published data on the acceptability of hypnosis as a pain relief method for labour was identified. However, unpublished data indicated that 38% of pregnant women in an Australian study felt that they did not know enough about the method to make a choice about whether they would like to use it for labour (Madden, 2009). Despite this, 56% of the 120 pregnant women who participated agreed or strongly agreed that hypnosis should be available as a pain relief method in Australian hospitals (Madden).

Psychological interventions including relaxation strategies and hypnosis are non-pharmacological methods for pain management, which have a long history in maternity care, as outlined in the following section.

Early history of hypnosis for childbirth. The use of psychological methods for comfort in childbirth has a very long history and concentrated forms of suggestion were reportedly used in Egyptian and Chinese societies (Bonica, & McDonald, 1990).

Platonov (1960) reported that following the development of medical hypnosis in the 1840s, physicians soon adopted the method for use during childbirth.

Medical interest in the use of hypnosis as a method of pain management for childbirth can be traced right through the 20th Century, for example, there are several enthusiastic case reports by early European practitioners, such as a case series of 79 obstetric patients published by Schultz-Rhonhof in 1922 (cited in Michael, 1952). Interest in hypnosis in maternity settings appeared to peak in the 1950s and 1960s but declined following improvements in pharmacological analgesia (Simkin & Bolding, 2004).

Although hypnosis has a long history, Gamsa (2003) noted that there continues to be considerable debate about what hypnosis is and the mechanisms underlying its effects. The following section outlines the theoretical conceptualizations of hypnosis.

What is hypnosis? Traditionally the theoretical debate about the nature of hypnosis has been conceptualised as two broad groups, "state" theorists and sociocognitive theorists. "State" theorists such as Hilgard (1969) argued that hypnosis represented a distinct state of conscious awareness. Socio-cognitive theorists such as Spanos and Chaves (1989) rejected the notion of hypnosis as a special "state" and argued that the behaviour associated with hypnosis reflected ordinary social behaviour that was shaped through social influence and cognitive skills. Kirsch and Lynn (1995) noted that although there was considerable controversy about the nature of hypnosis, the field was multifaceted and could more usefully be conceptualised as points on a continuum rather than as dichotomous positions. Gamsa (2003) stated that regardless of theoretical debates, the key components of hypnosis were generally agreed to involve reduced awareness of external stimuli, focused attention as well as increased absorption in and responsiveness to suggestions. Several basic steps have been identified as common across hypnotic techniques "(a) the patient's interest and cooperation are

obtained, (b) the range of attention is narrowed, (c) attention is directed inwards, and usually, (d) a deeply relaxed state is induced" (Gamsa, 2003 p. 527). Gamsa notes that for hypnosis focused on pain management, the hypnotherapist usually follows up by offering verbal suggestions aimed at increasing the client's comfort and developing imagery to reduce pain. In the context of childbirth, a wide range of suggestions and images may be directed at increasing feelings of relaxation, wellbeing and may also include developing sensations of analgesia such as numbing.

Neuro-imaging studies have provided evidence about the nature of neuro-physiological changes during hypnosis generally and during hypnotically induced analgesia specifically (Faymonville et al., 2000; Maquet et al., 1999). A positron emission tomography and magnetic resonance imaging study found hypnosis reduced pain experienced from a hot, noxious stimuli and that the process was mediated by the anterior cingulate cortex (Faymonville et al., 2000). The study found that both the affective and sensory aspects of pain perception were reduced when participants used hypnosis.

The study by Rainville et al. (1997), discussed above in the section on the affective and sensory dimensions of pain, used hypnosis as the experimental method to selectively alter the degree of unpleasantness of a hot, noxious stimuli without changing the perceived intensity of the pain. Although the study was aimed at differentiating the cortical areas involved the experience of these two dimensions of pain, it also demonstrated that hypnotic suggestions could be used to target a specific component of pain perception.

In the context of pain management for childbirth, hypnosis is generally considered alongside other non-pharmacological methods as focused on the affective aspects of the pain experience such as reducing anxiety, fear, muscular tension as well as enhancing mood and increasing the woman's sense of control (Simkin & Bolding,

2004). However, there have been case reports of hypnosis used as the only analgesia for surgical procedures, including caesarean section, for highly hypnotisable individuals (for example, Kroger & DeLee, 1957). The concept of hypnotisability and a potential relationship with pain relief for childbirth is briefly explained in the following section.

Hypnotisability

Hypnotisability refers to the degree to which individuals follow suggestions during hypnosis and Gamsa (2003) noted that a number of scales have been constructed to measure and predict hypnotic suggestibility. Some studies have found that highly hypnotisable individuals experienced greater pain relief than those who scored low on hypnotisability scales (for example, Harmon, Hynan, & Tyre, 1990) while other studies did not replicate this finding (for example, Rock, Shipley, & Campbell, 1969; Samko & Schoenfeld, 1975). Hypnotisability may not be a stable trait as some evidence has suggested that repeated practice and even the hormonal changes associated with pregnancy may affect individuals' responsiveness to hypnosis. For example, a study by Lewis (1992) found that the ability to control pain improved with training in hypnoanalgesia. A recent South Australian study also found that women were significantly more hypnotisable when they were pregnant than one to two years after their baby was born (Alexander, Turnbull, & Cyna, 2009). This study used a repeated-measures design with 37 women and found a large, clinically meaningful effect (d = 0.84) for increased hypnotisability during pregnancy. It measured hypnotisability using the Creative Imagination Scale (CIS) (Barber & Wilson, 1979), which has a maximum score of 40. The women's mean CIS score when pregnant was 23.5 (standard deviation (*SD*) 6.9), compared with a mean CIS score of 18.7 (*SD* 6.6) when the women were between 14 and 28 months postpartum (Alexander et al., 2009). Maternal hypnotisability will be assessed as a potential moderating variable on the effect of hypnosis on pain management for childbirth.

The following section describes the common methods used to provide hypnosis interventions.

Methods of hypnosis for childbirth. There are two main methods for providing hypnosis interventions for childbirth, hypnotherapy delivered in-person by a practitioner and self-hypnosis, where the woman is taught to enter hypnosis on her own or using an audio recording. Self-hypnosis can be taught to women individually or in groups and can be supplemented with audio-recordings for use at home. An example of a self-hypnosis intervention for childbirth is provided by Harmon et al. (1990). In this study, groups of 15 pregnant women had one-hour hospital-based training sessions each week for six weeks. The women were also given audio-recordings of the hypnotic induction for daily practice leading up to the birth. Martin, Schauble, Rai and Curry (2001) suggest that the benefits of teaching women self-hypnosis before labour include the promotion of women's active participation and sense of control for managing anxiety and discomfort. Potential problems with self-hypnosis programs include the possibility that women may find it difficult to utilize hypnosis without assistance under the physical and psychological demands of labour and questions about how often self-hypnosis needs to be practiced to be effective. Hypnotherapy delivered in-person by a practitioner during labour has been used in some studies and may overcome these issues. For example, in a trial conducted by Rock et al. (1969) in Philadelphia, a trained medical student provided hypnosis to women in active labour. Rock et al. stated that this method of delivering the intervention was chosen as it was considered to be less time consuming than antenatal training and more predictable results were expected. However, this model is likely to be very resource intensive unless the practitioner providing the hypnosis is already assigned to care for the woman during labour (such as in the case of a medical student or midwife). The woman's sense of autonomy and participation may also be reduced using a practitioner-led method, even with informed

consent and information that the experience will be under her control. The method of providing hypnosis, as well as the timing and quantity of hypnosis sessions all have the potential to moderate the effect of hypnosis interventions on pain management for childbirth. Several potential moderating variables relating to the nature and timing of the hypnosis intervention will be explored in the current study. These are: a) timing of first hypnosis session, b) whether hypnosis was provided antenatally or during labour, c) number of hypnosis session, d) number of participants in the sessions and e) provision of an audio-recording.

The following section outlines the current evidence about the effectiveness of hypnosis for pain management generally as well as evidence regarding the safety and effectiveness of hypnosis for pain management for childbirth specifically.

Current evidence regarding hypnosis for pain management. There is promising evidence that hypnosis may be effective in reducing acute pain across a range of settings including burns treatment and invasive medical procedures (Montgomery, Duhamel, & Redd, 2000; Patterson & Jensen, 2003). In a meta-analysis of 18 studies of experimentally induced and clinical pain, Montgomery et al. (2000) found that hypnotic analgesia provided a moderate to large analgesic effect for both types of pain. Although most of the participants were reported to be randomly assigned to treatment or control conditions, almost all of the trials included in that study were small and there was no explicit assessment of potential sources of selection, attrition and selective reporting bias in the trials. A Cochrane Review of clinical hypnosis for acute pain in adults is planned which will include explicit assessment of bias (Hallquist, Jensen, Patterson, Lynn, & Montgomery, 2007).

Patterson and Jensen (2003) also reported that several well-designed controlled trials supported the efficacy of hypnosis for both acute procedural pain and chronic pain conditions. That review included three studies on hypnosis for childbirth. One study

found no differences between women in the hypnosis condition and those in the control condition (Freeman, Macaulay, Eve, & Chamberlain, 1986). The other two studies reported positive effects of hypnosis on labour outcomes and pain relief (Davidson, 1962; Harmon et al., 1990) although the study by Davidson (1962) did not involve randomisation of participants. The Patterson and Jensen review provided more detailed information about each trial but again did not explicitly assess potential sources of bias.

Several reviews have been completed specifically examining the effects of hypnosis in maternity care. A narrative review by Brown and Hammond (2007) included randomised controlled trials and non-randomised studies of hypnosis in obstetrics. It included assessment of pain management but had a particular focus on several case studies of hypnosis for premature labour. Brown and Hammond reported that hypnosis reduced the use of analgesia and length of labour. It noted whether studies were randomised controlled trials but the review did not systematically assess of potential sources of selection, attrition and selective reporting bias in the trials. A more recent methodological review of hypnosis for pain in childbirth by Landolt and Milling (2011) assessed 13 randomised controlled trials and non-randomised studies. It also reported that self-hypnosis and practitioner led hypnosis were more effective than standard medical care, supportive counseling and childbirth education for management of pain in labour. Although that review is quite recent, it did not include two recently published randomised controlled trials of hypnosis for pain management for labour (Cyna, 2011; Fisher, Esplin, Stoddard, & Silver, 2009). The Landolt and Milling review provided more comprehensive and systematic detail about included studies in terms of the type of participants included in each study and the nature of the hypnosis intervention. However, the major weakness of that study was the lack of assessment of potential sources of attrition and selective reporting bias. The research did assess whether participants were randomly assigned to treatment conditions and it assessed

five trials (Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001; Mehl-Madrona, 2004; Rock et al., 1969) to have used random assignment, although two of these trials were quasi-randomised controlled trials so were at high risk of selection bias (Harmon et al., 1990; Rock et al., 1969).

The current study will involve explicit assessment of potential sources of selection, performance, detection, attrition and reporting bias, overcoming the shortcomings of the earlier reviews outlined above.

Two methodologically rigorous meta-analyses have been conducted on hypnosis for pain management for labour. Cyna, McAuliffe and Andrew (2004) identified five randomised controlled trials and 14 non-randomised comparisons but only three trials were able to be included in the meta-analysis (Harmon et al., 1990; Martin et al., 2001; Rock et al., 1969). It found that women who used hypnosis were less likely to use pharmacological analgesia than women in the control condition (relative risk = 0.51, 95% CI 0.28, 0.95) and concluded that further well designed trials were needed to provide evidence about the effects of hypnosis for childbirth. The safety of hypnosis in maternity care was also considered as part of that review. There were no reports of adverse effects from the hypnosis intervention in the studies included in the review but two previously published reports of maternal mental disturbances were noted. In one case a pregnant woman experienced psychotic symptoms and believed she had been sexually assaulted by her doctors (Werner, Schauble, & Knudsen, 1982) and in the other case a woman experienced postpartum anxiety and compulsive counting behaviour following the use of a counting strategy as part of hypnosis for labour (Cyna, 2003). Any adverse outcomes believed to be related to hypnosis for the trials included in the current study will be noted.

The most comprehensive assessment of high quality trials of hypnosis for pain management for childbirth to date was contained in the Cochrane Review of

complementary and alternative therapies for pain management (Smith, Collins, Cyna, & Crowther, 2006). Five randomised and quasi-randomised controlled trials evaluating hypnosis for childbirth (Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001; Mehl-Madrona, 2004; Rock et al., 1969) were included in the review and meta-analysis. Smith et al. reported that women taught self-hypnosis used less pharmacological analgesia (RR 0.70, 95% CI 0.36 to 0.79) and were more satisfied with pain management in labour (RR 2.33, 95% CI 1.15 to 4.71) than women randomised to control conditions. It was concluded that hypnosis may be beneficial as a method of pain management in labour but noted that only a small number of women had been studied. The review included an explicit assessment of potential sources of bias.

Rationale for the Current Review

The current review follows the same rigorous methodology as the earlier Cochrane Review by Smith et al. (2006). Importantly, it updates the findings of that review following the completion of a large Australian randomised controlled trial of hypnosis for pain management in childbirth (Cyna, 2011) as well as a smaller US based trial (Fisher et al., 2009). The current study also forms the basis of a new, stand-alone Cochrane Review of hypnosis for pain management for labour and childbirth (Madden, Middleton, Cyna, Matthewson, & Jones, in press). It provides a much more detailed examination of the intervention and its effectiveness than was possible in the earlier combined review. The results of this new review are also included in the recently completed Cochrane overview of systematic reviews of pain management techniques for pain management for women in labour (Jones et al., 2012). The current study provides updated meta-analytic data to inform pregnant women and their care providers about the effects of hypnosis for pain management during childbirth. This is important as there is increasing interest among expectant parents and some health care providers about the use of hypnosis for childbirth (Simkin & Bolding, 2004) with at least two

programs currently available for community-based preparation (Howell, 2009; Mongan, 2005). The inclusion of the results of the current study in the overview of systematic reviews further informs consumers and care providers by contributing to a summary of the evidence for a range of interventions to manage pain in labour (Jones et al., 2012).

Aim

This study aims to assess the effectiveness of hypnosis for pain management for childbirth.

The dependent variables are:

- Use of pharmacological pain relief or anaesthesia at any time during labour and childbirth (as defined by trialists);
- Satisfaction with pain relief (as defined by trialists);
- Sense of coping with labour (as defined by trialists);
- Spontaneous vaginal birth;
- Assisted vaginal birth;
- Caesarean section; and,
- Use of epidural/neuroaxial block as additional analgesia (as defined by trialists).

A secondary aim of this meta-analysis is to examine the impact of potential moderator variables based on those identified as part of the literature review. These are:

- Parity;
- Maternal hypnotisability;
- Timing of first hypnosis session;
- Whether hypnosis was provided antenatally or during labour;
- Number of hypnosis sessions;
- Number of participants in the sessions; and,

- Provision of an audio-recording.

Methods

Inclusion and Exclusion Criteria

The review included randomised-controlled trials and quasi-randomised controlled trials comparing hypnosis with placebo, no treatment and any analgesic drug or technique for pain management for labour. Cluster randomised trials and trials using a crossover design were not included. There was no minimum sample size specified and no restrictions on when the trial was conducted. There was no restriction on the geographical location of the trials.

The eligible participant population was pregnant women. There were no restrictions for the inclusion of trials based on participant's cultural background, age or parity.

Operational Characteristics of Variables

The independent variable was hypnosis. The hypnosis condition included the use of hypnosis in preparation for and/or during labour, with or without concurrent use of other pain relief methods.

A large number of primary and secondary dependent variables were pre-specified and were reported fully in Madden et al. (in press). All of the primary dependent variables are reported here. Only the secondary dependent variables that provide specific additional information regarding the primary dependent variables are reported. This focus on reporting only the key outcomes was designed to meet specifications regarding the length of the thesis document.

The primary dependent variables were:

- Use of pharmacological pain relief or anaesthesia at any time during labour and childbirth (as defined by trialists);

- Satisfaction with pain relief (as defined by trialists);
- Sense of coping with labour (as defined by trialists); and,
- Spontaneous vaginal birth.

The secondary dependent variables were:

- Assisted vaginal birth (additional information regarding mode of birth);
- Caesarean section (additional information regarding mode of birth); and,
- Use of epidural/neuroaxial block as additional analgesia (additional information regarding use of pharmacological pain relief).

Moderator Analyses

The following potential moderators were examined:

- Parity;
- Maternal hypnotisability;
- Timing of first hypnosis session;
- Whether hypnosis was provided antenatally or during labour;
- Number of hypnosis sessions;
- Number of participants in the sessions; and,
- Provision of an audio-recording.

Parity. Where studies provided data on parity, women were classified into two groups; nulliparous (that is women who had never previously given birth) and parous (women who had previously given birth).

Maternal hypnotisability. Hypnotisability can be assessed using a range of scales such as the Creative Imagination Scale (CIS) (Barber & Wilson, 1979) or the Harvard Group Scale of Hypnotic Suggestibility (Shor & Orne, 1962). The Harvard Group Scale of Hypnotic Suggestibility is one of the most widely used scales assessing hypnotic susceptibility (Barnes, Lynn & Pekala, 2008). Both the Harvard Scale and the CIS have

been reported to have adequate psychometric properties in terms of reliability and validity (Sheehan & McConkey, 1979, Wilson & Barber, 1978). Where studies provided data on the hypnotisability of the participants, women were grouped into high and low hypnotic susceptibility categories. The definition of high and low hypnotic susceptibility was defined by the trialists for each study.

Timing of first hypnosis session. The participants' trimester of pregnancy when the first session of hypnosis was provided was coded as 1st trimester (up to 12 weeks of pregnancy), 2nd trimester (13 to 28 weeks) and 3rd trimester (29 weeks onwards). Where studies began hypnosis in more than one trimester, the study was coded separately (for example 1st and 2nd trimester).

Whether hypnosis was provided antenatally or during labour. Studies were coded by whether they provided the hypnosis intervention during pregnancy (antenatal) or during labour (labour).

Number of hypnosis sessions. The number of hypnosis sessions provided in the studies was classified as less than four sessions or as four or more sessions. As there is no established criteria for categorising the number of sessions, these groupings were based on the clinical judgement of the Cochrane Review authors with experience in hypnosis for labour.

Number of participants in the hypnosis sessions. The number of participants in the hypnosis sessions was coded as individual if the participant had one-on-one sessions with the hypnotherapist and group if more than one participant was involved in the sessions.

Provision of an audio-recording. The audio-recording variable was classified according to whether participants were provided with audio-recorded hypnosis sessions for practices at home or not. Three categories were coded, if participants received live hypnosis and an audio-recording for home practice it was coded hypnosis plus audio

CD/tape, if participants received live hypnosis but no audio-recording it was coded hypnosis, no audio CD/tape and if participants did not have live hypnosis but did receive an audio-recording it was coded nurse/audio CD only.

Searches

Searches were conducted of the Cochrane Pregnancy and Childbirth Group's Trials Register (to January 2012), the Cochrane Central Register of Controlled Trials (The Cochrane Library 2012), MEDLINE (1966 to 2012), EMBASE (1980 to 2012), and CINAHL (1980 to 2012). For detailed information about these searches see Appendix A. An electronic search was also conducted on PsychINFO (1966 to 2011) using CSA Illumina on January 27, 2011. This search included a cluster of terms for hypnosis, a cluster of terms focused on pain, analgesia and anaesthesia and a cluster of terms focused on labour and birth. For the full text of the PsychINFO search see Appendix B. A search was also made by the author of the reference lists of the earlier systematic review by Cyna, McAuliffe and Andrew (2004) as well as the reference lists of the primary studies identified for inclusion in the review. No language restrictions were applied and unpublished studies were eligible for inclusion in the review.

In addition to the author, several individuals were involved in identification and assessment of studies for inclusion. Mohammad Othman and Leanne Jones are Research Associates with the Cochrane Pregnancy and Childbirth Review group and have both completed several Cochrane Reviews. Philippa Middleton is the Executive Director of the Australian Research Centre for the Health of Women and Babies and is an Editor with the Cochrane Methodology group.

Abstracts for the studies identified from the PsychINFO search were independently assessed by the author and Philippa Middleton. Full text articles were downloaded for any study that appeared to meet the selection criteria. The author assessed the full text articles for eligibility. Mohammad Othman assessed full-text

copies of the studies identified in the other electronic searches using the same criteria. The author and Leanne Jones checked each of these assessments. Any disagreement was resolved by discussion. Reasons for exclusion for any trials have been reported.

Coding Procedures

The author and either Mohammad Othman or Leanne Jones, independently extracted data from each study and assessed the studies for bias using a data extraction form (See Appendix C). Leanne Jones and Philippa Middleton also checked all data extraction and assessments. Any discrepancies in data extraction were resolved through discussion between the author and Leanne Jones. Data was entered into Review Manager software (RevMan, 2011) by the author or Mohammad Othman and checked for accuracy by Leanne Jones and Philippa Middleton.

Assessment of Study Quality

Two researchers (the author and Mohammad Othman or Leanne Jones) independently assessed risk of bias for each study using the Cochrane Handbook criteria (Higgins & Green, 2011). Any discrepancies were resolved through discussion. The assessment of bias for each trial included description of sequence generation and allocation concealment, checking for selection bias; blinding of participants, care providers and outcome assessors, checking for performance bias; incomplete outcome data, checking for attrition bias through withdrawals, dropouts and protocol deviations; selective reporting bias as well as an overall risk of bias. For detailed information on the assessment of bias process and the criteria used to classify each aspect of trials at high or low risk of bias see Appendix D. Where selective reporting bias was suspected, attempts were made to contact study authors to seek missing outcome data.

For included studies, levels of attrition were noted. If enough trials were identified it was planned to explore the impact of including studies with high levels of

missing data in the overall assessment of treatment effect using sensitivity analysis. All outcomes analyses were carried out, as far as possible, on an intention-to-treat basis.

Statistical Methods

A statistical analysis of treatment effects was conducted using the Review Manager software (RevMan, 2011). For dichotomous data, results were presented as summary risk ratio with 95% confidence intervals. For continuous data, mean difference was used if outcomes were measured in the same way between trials. The standardised mean difference was used to combine trials that measured the same outcome, but used different methods. The method of analysis for ordinal data was determined by the type of scale used to measure the data and the availability of sufficient information to allow conversion to continuous or dichotomous data. Ordinal data measured on scales with many points (e.g. pain measured on visual analogue scales) was analysed as continuous data and the intervention effect was expressed as a difference in means or standardised difference in means. Ordinal data measured on shorter ordinal scales (e.g. excellent, very good, good) was analysed as dichotomous data by combining categories (e.g. excellent and very good) and the intervention effect was expressed using risk ratios.

Statistical heterogeneity was measured in each meta-analysis using the Tau^2 (T^2), I^2 index and Chi^2 (χ^2) statistics. Heterogeneity was considered to be substantial if I^2 was greater than 30% and either T^2 was greater than zero, or there was a low p value (less than 0.10) in the Chi^2 test (χ^2) for heterogeneity (Gates, 2010). Moderation effects were explored for primary outcomes as a potential source of heterogeneity. The results of the Chi^2 test (χ^2) for differences between the subgroups for potential moderation variables were reported.

There is ongoing debate about the conditions under which fixed-effect or random-effects meta-analysis should be utilized (Gates, 2010). In this study random-effects meta-analysis was selected as there was clinical heterogeneity sufficient to

expect that the underlying treatment effects would differ between trials and substantial statistical heterogeneity was detected (Gates, 2010). The results of random-effects analyses have been presented as the average treatment effect with the 95% confidence interval, and the estimates of T^2 and I^2. However, given the debate regarding the appropriate model, particularly under circumstances where there are few studies available (Higgins & Green, 2011), the results of fixed-effect meta-analysis have been presented for comparison as Appendix E.

Ethical Considerations

The study obtained a certificate of exemption from ethical review from the Human Research Ethics Committee (Tasmania).

Results

Results of the Search

The search strategy generated 188 abstracts, which were reviewed to assess if they included information relevant to the study. In total 12 trials were identified. Two large randomised controlled trials are ongoing in the United Kingdom (Downe, 2011) and Denmark (NCT00914082, 2009), so results are not yet available. Three other trials were excluded; one was not a randomised or quasi-randomised controlled trial (Mairs, 1995), in one the intervention was not for pain management in childbirth (Guse, Wissing, & Hartman, 2006) and for the final study no English translation was available (Hao, Li, & Yao, 1997). Seven studies reporting data on 1213 women were included in this review.

Authors of four of the studies (Cyna, 2011; Fisher et al., 2009; Martin et al., 2001; Mehl-Madrona, 2004) were contacted for further information about the methods and/or additional data. Further data and information was received for two studies (Cyna, 2011; Mehl-Madrona, 2004). In addition, dissertations containing additional data and information regarding methodology were obtained for three studies (Cyna, 2011; Harmon et al., 1990; Martin et al., 2001).

Characteristics of Included Studies

Key descriptive information regarding the included studies is shown in Table 1. All seven studies were parallel design comparing self-hypnosis or hypnotherapy with a control group. As shown in Table 1, two studies were quasi-randomised controlled trials (Harmon et al., 1990; Rock et al., 1969) and the remaining studies were randomised controlled trials. Study sample size ranged from 38 (Fisher et al., 2009) to 520 (Mehl-Madrona, 2004). Five of the studies were conducted in the USA (Fisher et al., 2009; Harmon et al., 1990; Martin et al., 2001; Mehl-Madrona, 2004; Rock et al., 1969), one

in the UK (Freeman et al., 1986) and one in Australia (Cyna, 2011) (see Table 1). Participants were generally healthy pregnant women and one study restricted inclusion to only adolescents aged 18 years or younger (Martin et al., 2001). The control groups involved: standard childbirth preparation (Fisher et al., 2009; Freeman et al., 1986); usual care (Cyna, 2011; Rock et al., 1969), a relaxation tape combined with relaxation practice in antenatal classes (Harmon et al., 1990); supportive counselling (Martin et al., 2001); and supportive psychotherapy (Mehl-Madrona, 2004). For the purposes of this review supportive psychotherapy, supportive counselling and the relaxation tape with relaxation practice in antenatal classes were treated as attention control conditions where participants received a similar or the same amount of contact as those in the intervention group. As shown in Table 1, not all of the studies included data for the all of the outcomes being assessed. For example, most of the studies reported on use of pharmacological analgesia and spontaneous vaginal birth but there was no data available in a format suitable for analysis for women's sense of coping with labour.

Table 1.

Key Characteristics of Included Studies Examining the Effect of Hypnosis for Pain Management for Childbirth

First author	Year	Country	Participants Hypnosis: Control (*n*)	Study design	Inclusion criteria	Intervention Hypnosis (H), Control (C)	Relevant outcomes measured[a]
Cyna	2011	Australia	154:151 (Nurse/CD group 143)	Randomised controlled trial	Healthy women > 34 and < 39 weeks gestation, with a singleton, viable fetus, vertex presentation, who are not in active labour and who are planning a vaginal birth.	H = Live antenatal training with hypnotherapist + audio CD C = Usual care Nurse/CD = Antenatal training with nurse + audio CD	1, 2*, 3, 4*, 5, 6, 7
Fisher	2009	USA	17:21	Randomised controlled trial	Women interested in childbirth preparatory courses	H = antenatal Hypnobirthing classes C = Standard childbirth preparation	1*, 3*, 4*, 5*, 6*, 7*
Freeman	1986	UK	29:36	Randomised controlled trial	Normal pregnancy and a desire to avoid epidural anaesthesia	H = Individual hypnosis sessions C = Standard childbirth preparation	1, 3, 5, 7
Harmon	1990	USA	30:30	Quasi Randomised controlled trial	Women aged 18 to 35 years, nulliparous, married, white, during the end of the second trimester of pregnancy.	H = Live and audio tape hypnosis sessions and Ischemic Pain Task C = Relaxation classes and audio tape (control) and Ischemic Pain Task	1, 3, 5,

Martin	2001	USA	22:20	Randomised controlled trial	Teenage patients (18 years or younger at the time of conception) before the end of their 24th week of pregnancy	H = Individual training in self-hypnosis C = Supportive counselling	1, 3, 5, 6
Mehl-Madrona	2004	USA	260:260	Randomised controlled trial	Women in the first or second trimester, low risk pregnancies and no DSM-IV psychiatric diagnosis	H = Individual hypnosis sessions C = Supportive psychotherapy	1, 3*, 5*, 6, 7
Rock	1969	USA	22:18	Quasi Randomised controlled trial	Women at term, with no obstetric complications, in labour and not more than 4cm dilated	H: Individual hypnosis during labour C: Usual care	1, 7

[a]Outcomes 1 = Use of pharmacological analgesia, 2 = Satisfaction with pain relief, 3 = Spontaneous vaginal birth, 4 = Sense of coping with labour 5 = Assisted vaginal birth, 6 = Caesarean section, 7 = Use of epidural/neuroaxial block

* measured but not reported in a format that could be included in the data analysis

Description of Interventions and Classification of Moderator Variables

In five studies the intervention was antenatal self-hypnosis (Cyna, 2011; Fisher et al., 2009; Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001) which was taught in group classes (Cyna, 2011, Fisher et al., 2009; Harmon et al., 1990) or during individual consultations (Freeman et al., 1986; Martin et al., 2001) (see Table 1). In one study the intervention was individual hypnotherapy provided antenatally (Mehl-Madrona, 2004) and in one study the intervention was hypnosis provided during labour (Rock et al., 1969). As shown in Table 1, one trial had two intervention groups as well as the usual care control group (Cyna, 2011). In one intervention group, women had 'live' hypnosis in antenatal classes led by a hypnotherapist and a hypnosis audio CD was provided for home practice (Cyna, 2011). In the other intervention group, women listened to the same hypnosis audio CD at antenatal classes led by a nurse without training in hypnosis and were also provided with the audio CD for home practice (Cyna, 2011). The live hypnosis intervention was most similar to the other antenatal self-hypnosis trials so was included in the main comparisons for this study. Provision of an audio-recording was identified as a potential moderating variable and moderator analysis was conducted comparing women in each group with those in the control condition.

The hypnosis intervention began in the first or second trimester of pregnancy in one study (Mehl-Madrona, 2004), in the second trimester in one study (Martin et al., 2001) and in the third trimester in three studies (Cyna, 2011; Freeman et al., 1986; Harmon et al., 1990) (see Table 2). The intervention began during labour in one study (Rock et al., 1969). It was not clear when in the pregnancy the intervention began in one study (Fisher et al., 2009). Three studies involved weekly intervention sessions (Cyna, 2011; Freeman et al., 1986; Harmon et al., 1990. In one study these sessions started at 32 weeks gestation and continued until the birth (Freeman, 1986). In one study a series

of six weekly classes were scheduled (Harmon et al., 1990) and in one study there were three, weekly intervention sessions starting as closely as possible to 37 weeks gestation (Cyna, 2011). In two studies women were also provided with an audio recording for daily practice at home (Cyna, 2011; Harmon et al., 1990). In one study there were four intervention sessions spanning approximately 8 weeks (Martin et al., 2001). One study reported that women could attend for hypnotherapy as often as desired (subject to therapist availability) (Mehl-Madrona, 2004). It was not clear how many intervention sessions were provided for one study (Fisher et al., 2009). In the study where hypnosis was provided during labour, the hypnotherapist was a medical student who also performed routine labour assessments (Rock et al., 1969). The hypnotic induction took an average of 20 minutes and it was reported that the total time added by the hypnotic procedures was 45 minutes longer than with usual care (Rock et al., 1969).

Table 2 shows the classification and coding for potential moderator variables across the included studies.

Table 2.
Classification of Potential Moderator Variables

First author	Parity	Hypnostizability	Trimester of intervention	Antenatal or labour intervention	Number of hypnosis sessions	Individual or group sessions	Use of audio CD
Cyna	Nulliparous and parous	Measured as high and low	3rd	Antenatal	3 (<4)	Group	Yes
Fisher	Unclear	Unclear	Unclear	Antenatal	Unclear	Group	Unclear
Freeman	Nulliparous	Measured but not reported in detail	3rd	Antenatal	9 (4+)	Individual	No
Harmon	Nulliparous	Measured as high and low	3rd	Antenatal	6 (4+)	Group	Yes
Martin	Nulliparous and parous	Not measured	2nd	Antenatal	4 (4+)	Individual	No
Mehl-Madrona	Nulliparous and parous	Not measured	1st and 2nd	Antenatal	Unlimited (4+)	Individual	No
Rock	Nulliparous and parous	Not measured	3rd (in labour)	Labour	1 (<4)	Individual	No

Risk of Bias in Included Studies

Selection bias. As shown in Table 3, two of the trials were rated as low risk of selection bias for random sequence generation, having used a computer-generated random number sequence (Cyna, 2011) and a random number generator (Mehl-Madrona, 2004). Three trials did not report how the random sequence was generated and were rated as unclear risk of bias (Fisher et al., 2009; Freeman et al., 1986; Martin et al., 2001). Two of the trials were rated as high risk of bias as they were quasi-randomised controlled trials where women were allocated to groups based on hospital history number (Rock et al., 1969) and the month the woman was due (Harmon et al., 1990). One trial was rated as low risk of bias for allocation concealment as the researchers were provided with group allocations using a centralised telephone system and later a password protected computer database system (Cyna, 2011). Four trials were rated as unclear risk of bias as they did not report how group allocation was concealed (Fisher et al., 2009; Freeman et al., 1986; Martin et al., 2001; Mehl-Madrona, 2004). Two studies were rated as high risk of bias (Harmon et al., 1990; Rock et al., 1969) (see Table 3). Both studies were quasi-randomised controlled trials so were potentially at high risk that those enrolling participants may foresee group assignment. This assessment was made despite attempts in one trial to conceal the patient history number until after the woman had been examined and the decision made that she met all the criteria for the study (Rock et al., 1969).

Table 3.
Assessment of Risk of Bias for Included Studies

First author	Random sequence allocation	Allocation concealment	Blinding of participants (objective outcomes)	Blinding of participants (subjective outcomes)	Blinding of personnel	Blinding of outcome assessment	Incomplete outcome data	Selective reporting bias	Other bias
Cyna	Low risk	Low risk	Low risk	High risk	Low risk	Low risk	Low risk	Low risk	Low risk
Fisher	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	Low risk
Freeman	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear	High risk	Unclear	Unclear
Harmon	High risk	High risk	Low risk	Unclear	Unclear	Low risk	Low risk	Low risk	Unclear
Martin	Unclear	Unclear	Low risk	Unclear	Low risk	Unclear	Low risk	Low risk	Low risk
Mehl-Madrona	Low risk	Unclear	Unclear	Unclear	Unclear	Low risk	High risk	High risk	Unclear
Rock	High risk	High risk	Low risk	Unclear	High risk	Unclear	Low risk	Unclear	Unclear

Note: See Appendix D for full criteria for high/unclear/low risk ratings for each domain

Blinding (performance bias and detection bias). Blinding of participants is difficult for hypnosis interventions but four trials reported that women were not told the group to which they were allocated (Cyna, 2011; Harmon et al., 1990; Martin et al., 2001; Rock et al., 1969). It was judged that participants' knowledge of their group allocation may have an impact on subjective outcomes (such as satisfaction with pain relief) but was unlikely to have an impact on objective outcomes (such as spontaneous vaginal birth). As shown in Table 3, risk of bias was assessed separately for subjective and objective outcomes where studies reported that blinding of participants had been attempted. Four studies were rated as low risk of bias for objective outcomes (Cyna, 2011; Harmon et al., 1990; Martin et al., 2001; Rock et al., 1969). Three studies were rated as unclear risk of bias for subjective outcomes (Harmon et al., 1990; Martin et al., 2001; Rock et al., 1969) as women were not told their group allocation but there was no reporting about whether blinding was successful. Only one trial reported data about the success of blinding for participants (Cyna, 2011). This trial was rated at high risk of bias for subjective outcomes as Cyna (2011) reported that none of the women in the control group believed they were in a hypnosis group and more than 70% of women in the two intervention groups believed they were in a hypnosis group. Three studies were rated as unclear risk of bias for blinding of participants overall (Fisher et al., 2009; Freeman et al., 1986; Mehl-Madrona, 2004) as they did not report whether any attempt was made to blind the women to their group allocation.

It is not possible for personnel providing hypnosis interventions to be blinded to the intervention but it is possible for personnel caring for a woman in labour to be blinded so assessment of blinding of personnel in this review relates to blinding of the personnel who cared for the woman during labour. As shown in Table 3, blinding of personal was assessed as low risk of bias in two studies (Cyna, 2011; Martin et al.,

2001) and at high risk of bias for one trial (Rock et al., 1969). The risk of bias was unclear in the remaining studies (Fisher et al., 2009; Freeman et al., 1986; Harmon et al., 1990; Mehl-Madrona, 2004) as there was no reporting of whether personnel were blinded to group allocation.

Blinding of outcome assessment was at low risk of bias in three studies (Cyna, 2011; Harmon et al., 1990; Mehl-Madrona, 2004) and unclear in the remaining studies (see Table 3). Two studies did not report whether outcome assessors were blinded to group allocation (Fisher et al., 2009; Freeman et al., 1986) and in two studies it was unclear from what was reported whether outcome assessors were blinded (Martin et al., 2001; Rock et al., 1969).

Incomplete outcome data (attrition bias). Four of the trials were rated as low risk of bias for incomplete outcome data (Cyna, 2011; Harmon et al., 1990; Martin et al., 2001; Rock et al., 1969) (see Table 3). In one trial the intervention was provided in labour and no losses of participants were reported (Rock et al., 1969). In one study all primary and secondary outcomes for eligible trial participants were analysed using the intention to treat principle (Cyna, 2011). In one trial one woman was excluded following randomisation after becoming ineligible for inclusion in the study (Harmon et al., 1990). In one trial the reasons for the five participants lost to follow up were unlikely to have been related to the intervention or were balanced between groups (three moved out of the geographic area and one from each group did not complete the research protocol) (Martin et al., 2001). Two trials were assessed high risk of bias (Freeman et al., 1986; Mehl-Madrona, 2004). In one trial losses appeared to be related to the intervention, four participants from the hypnosis condition were excluded as they did not attend for hypnosis (Freeman et al., 1986). In the other trial women from the hypnosis group were excluded from data analysis if they were diagnosed with a range of mental illnesses but it was unclear whether women from the control group were

excluded on the same basis (Mehl-Madrona, 2004). In the remaining study risk of bias for incomplete outcome data was unclear as there was no reporting of how many participants were lost to follow-up (Fisher et al., 2009).

Selective reporting (reporting bias). Three of the trials were rated as low risk of bias for selective outcome reporting (Cyna, 2011; Harmon et al., 1990; Martin et al., 2001). In one trial all of the outcomes listed in the trial registration were reported or provided (Cyna, 2011), and in two trials all of the outcomes listed in the hypotheses were reported (Harmon et al., 1990; Martin et al., 2001) (see Table 3). One study was assessed as being at high risk of bias (Mehl-Madrona, 2004) as not all of the outcomes outlined in the study were fully reported. In the remaining three studies risk of bias for selective reporting was unclear (Fisher et al., 2009; Freeman et al., 1986; Rock et al., 1969) as one report was a conference abstract so detailed data were not reported (Fisher et al., 2009) and two studies reported narrative descriptions with *p* values without frequency data for one outcome (Freeman et al., 1986; Rock et al., 1969).

Other potential sources of bias. Three of the trials were rated as being at low risk of bias for other bias (Cyna, 2011; Fisher et al., 2009; Martin et al., 2001) based on balance in demographic characteristics of participants at baseline and no other issues of concern identified. In the remaining four studies risk of bias was unclear (Freeman et al., 1986; Harmon et al., 1990; Mehl-Madrona, 2004; Rock et al., 1969) as little or no demographic data were reported for the intervention and control groups (see Table 3).

Effects of Interventions

Use of pharmacological pain relief or anaesthesia during labour and childbirth.

All seven studies measured this outcome (Cyna, 2011; Fisher et al., 2009; Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001; Mehl-Madrona, 2004; Rock et al., 1969) but one study did not report any numerical data so could not be included in the analysis (Fisher et al., 2009). Two studies (Harmon et al., 1990; Rock et

al., 1969) reported the use of tranquillizers but these were not considered to be pain relief for the purposes of this review. Therefore, the data for (Harmon et al., 1990) and (Rock et al., 1969) used in this outcome relate to the use of narcotics only. One study (Freeman et al., 1986) combined women who used the inhaled analgesic Entonox with those who used no analgesia so only those who were reported as using pethidine and/or epidural were included as using pharmacological pain relief or anaesthesia.

As shown in Figure 1, there was a trend towards women in the hypnosis group being less likely to use pharmacological pain relief or anaesthesia during labour and childbirth, but this result did not reach statistical significance ($p = 0.06$, average (RR) 0.63, 95% (CI) 0.39, 1.01, 6 studies, 1032 women). The confidence interval was very wide, indicating that further evidence is needed to gain greater precision about the size of any effect. There was substantial statistical heterogeneity: $I^2 = 95\%$, $T^2 = 0.30$, χ^2 (5) = 91.01, $p < 0.01$, and so a random-effects model was used.

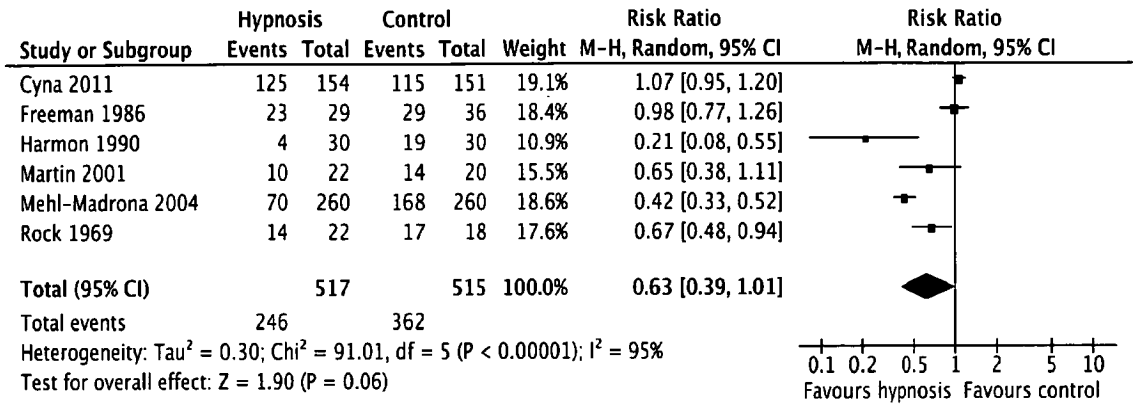

Figure 1: Forest plot of effect sizes for hypnosis on use of pharmacological analgesia

It is likely that the Harmon et al. (1990) and Mehl-Madrona (2004) trials contributed to the high level of heterogeneity. The Harmon et al. (1990) trial was a quasi-randomised controlled trial so is subject to a high risk of selection bias. The Mehl-Madrona (2004) trial provided unlimited one-on-one hypnotherapy commencing in the first or second trimester and was judged to be at high risk of attrition bias. It is not clear which of these factors, if any, contributed to the results favouring hypnosis.

Satisfaction with pain relief. One study reported on this outcome (Cyna, 2011). There was no significant difference between the hypnosis and control group in the proportion of women who reported that they received adequate pain relief (RR 1.06, 95% CI 0.94, 1.20, 1 study, 264 women).

Spontaneous vaginal birth. Six studies reported on this outcome (Cyna, 2011; Fisher et al., 2009; Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001; Mehl-Madrona, 2004), but data were only available for analysis from four studies (Cyna, 2011; Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001). One trial did not report numerical data for this outcome (Fisher et al., 2009) and one trial reported data grouped as 'uncomplicated births' and 'complicated births' (Mehl-Madrona, 2004).

Although the uncomplicated births group only included spontaneous vaginal births, the complicated births group included both spontaneous vaginal births and surgically assisted births. This meant that the overall number of spontaneous vaginal births could not be calculated (for example, if a woman had a spontaneous vaginal birth followed by a post-partum haemorrhage she was included in the complicated birth group) (Mehl-Madrona, 2004).

As shown in Figure 2, no significant difference was found between the hypnosis and control group in the proportion of women having a spontaneous vaginal birth (average RR 1.35, 95% CI 0.93, 1.96, 4 studies, 472 women). The confidence interval was very wide, indicating that further evidence is needed to gain greater precision about the size of any effect. There was substantial statistical heterogeneity: $I^2 = 82\%$, $T^2 = 0.11$, $\chi^2(3) = 16.31$, $p < 0.01$, and so a random-effects model was used.

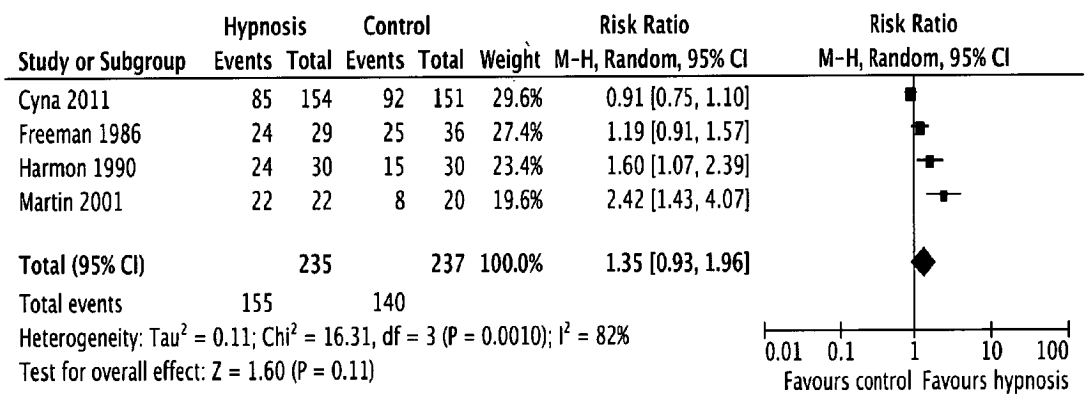

Figure 2: Forest plot of effect sizes for hypnosis for spontaneous vaginal birth

It is likely that the Martin et al. (2001) trial contributed to the high level of heterogeneity. That trial included only women aged 18 years or younger and involved hypnosis preparation for labour provided one-on-one from the second trimester. It is not clear which, if any, of these factors may help explain the heterogeneity.

Sense of coping with labour. Two studies reported on this outcome (Cyna, 2011, Fisher et al., 2009) but no frequency data were reported so the data were unable to be analysed

as part of the review. Cyna (2011) measured women's perceptions of coping with childbirth postnatally, prior to their discharge from hospital, and found there was no difference between the groups while Fisher et al. (2009) reported that postnatally, the Hypnobirthing group recalled relatively poorer intrapartum coping skills ($p = 0.02$).

Assisted vaginal birth. Six studies measured this outcome (Cyna, 2011; Fisher et al., 2009; Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001; Mehl-Madrona, 2004) but data were only available for analysis from four studies (Cyna, 2011; Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001). One study did not report numerical data for this outcome (Fisher et al., 2009) and one study grouped assisted vaginal births within a complicated birth group which included a range of complications as outlined above (Mehl-Madrona, 2004).

As shown in Figure 3, no significant difference was found in the proportion of women who had assisted vaginal births between the women in the hypnosis group and those in the control group (average RR 0.61, 95% CI 0.32, 1.15, 4 studies, 474 women). The confidence interval was very wide, indicating that further evidence is needed to gain greater precision about the size of any effect. There was substantial statistical heterogeneity: $I^2 = 52\%$, $T^2 = 0.20$, $\chi^2(3) = 6.20$, $p = 0.10$, and so a random-effects model was used. It did not appear that any individual trial was responsible for this heterogeneity.

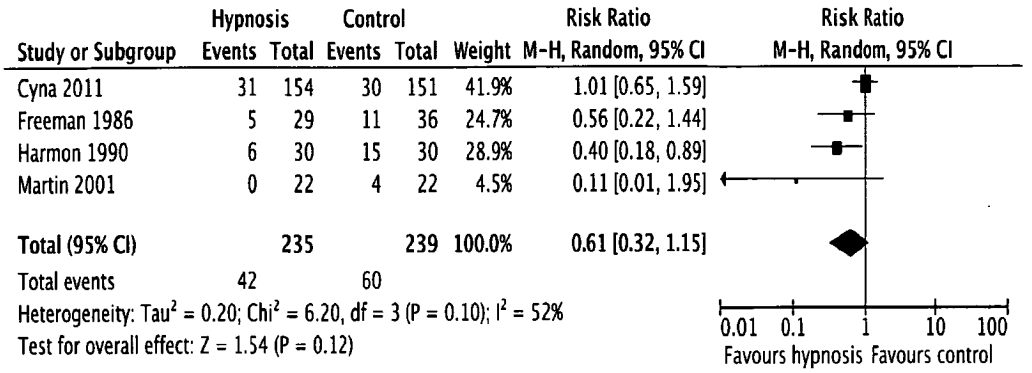

Figure 3: Forest plot of effect sizes for hypnosis for assisted vaginal birth

Caesarean section. Four studies reported upon this outcome (Cyna, 2011; Fisher et al., 2009; Martin et al., 2001; Mehl-Madrona, 2004), but one study did not report numerical data so was not able to be included in the analysis (Fisher et al., 2009). As shown in Figure 4, no significant difference was found in the proportion of women who had a caesarean section between those in the hypnosis group and the control group (average RR 0.58, 95% CI 0.20, 1.65, 3 studies, 867 women). The confidence interval was very wide, indicating that further evidence is needed to gain greater precision about the size of any effect. There was substantial statistical heterogeneity: $I^2 = 86\%$, $T^2 = 0.60$, $\chi^2(2) = 14.52$, $p < 0.01$, so a random-effects model was used.

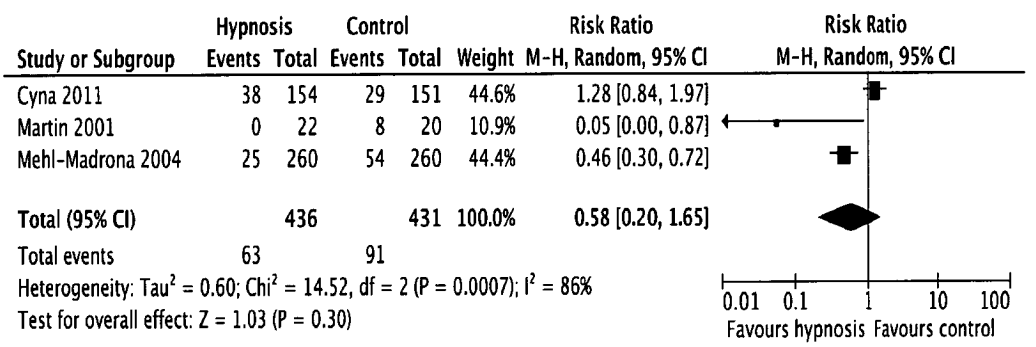

Figure 4: Forest plot of effect sizes for hypnosis for caesarean birth

It is likely that the Martin et al. (2001) trial contributed to the high level of heterogeneity. As noted previously, this trial included only women aged 18 years or

younger and involved hypnosis preparation for labour provided one-on-one from the second trimester. Again, it is not clear which, if any, of these factors may help explain the heterogeneity.

Use of epidural/neuroaxial block. Five studies reported on this outcome (Cyna, 2011; Fisher et al., 2009; Freeman et al., 1986; Mehl-Madrona, 2004; Rock et al., 1969), but one trial did not report numerical data so was not able to be included in the analysis (Fisher et al., 2009).

As shown in Figure 5, no significant difference was found in the proportion of women having an epidural between the hypnosis and control group (average RR 0.76, 95% CI 0.29, 2.02, 4 studies, 930 women). The confidence interval was very wide, indicating that further evidence is needed to gain greater precision about the size of any effect. There was substantial statistical heterogeneity: $I^2 = 94\%$, $T^2 = 0.74$, $\chi^2(3) = 49.78$, $p < .01$, and so a random-effects model was used.

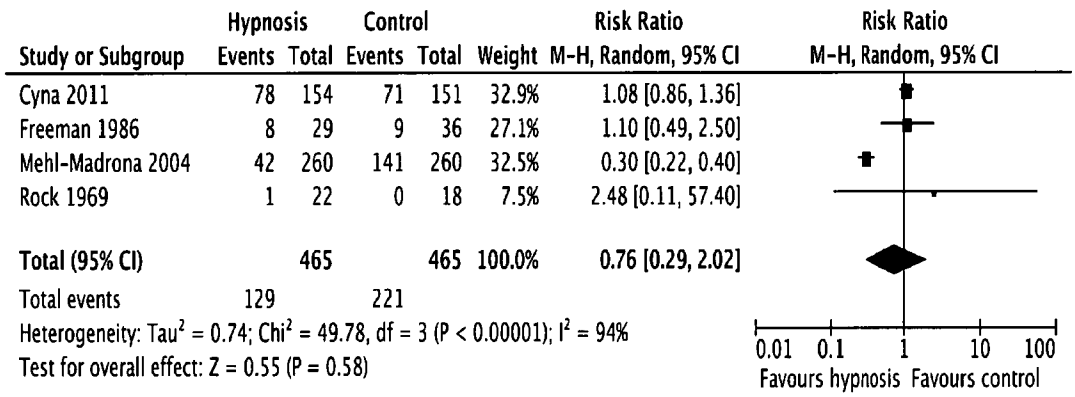

Figure 5: Forest plot of effect sizes for hypnosis on use of epidural/neuroaxial block

It appears that the Mehl-Madrona (2004) trial was responsible for the high level of heterogeneity. This trial provided unlimited one-on-one hypnotherapy commencing in the first or second trimester and was judged to be at high risk of attrition bias. It is not

clear which of these factors, if any, contributed to the results strongly favouring hypnosis.

Adverse effects. There were no reports of adverse effects attributed to the hypnosis intervention for any of the included trials.

Sensitivity Analysis

Sensitivity analysis was undertaken for the primary outcomes by excluding the two quasi-randomised controlled trials (Harmon et al., 1990; Rock et al., 1969) as these were at high risk of bias for selection bias. With the quasi-randomised studies included there was a trend towards women in the hypnosis group being less likely to use pharmacological pain relief or anaesthesia during labour and childbirth, but the difference between groups did not reach statistical significance ($p = 0.06$, average RR 0.63, 95% CI 0.39, 1.01, 6 studies, 1032 women). This trend was not found when the quasi-randomised controlled trials were excluded for this outcome ($p = 0.29$, average RR 0.73, 95% CI 0.41, 1.30, 4 studies, 932 women).

Only one of the quasi-randomised controlled trials provided data for the spontaneous vaginal birth outcome (Harmon et al., 1990). The results with this trial included found no significant difference between women in the hypnosis group and women in the control group (average RR 1.35, 95% CI 0.93, 1.96, 4 studies, 472 women). Similarly, no significant difference was found when the (Harmon et al., 1990) trial was excluded (average RR 1.29, 95% CI 0.83, 2.00, 3 studies, 412 women).

No data from the quasi-randomised controlled trials was available for the other primary outcomes.

Moderator Analyses

Moderator analyses were restricted to the primary outcomes and data were only available for two outcomes, use of pharmacological pain relief or analgesia and spontaneous vaginal birth. For use of pharmacological pain relief or analgesia the effect

of hypnosis was not moderated by parity $\chi^2(1) = 0.96$, $p = .33$, maternal hypnotisability $\chi^2(1) = 0.06$, $p = .81$, whether hypnosis was provided antenatally or during labour $\chi^2(1) = 0.07$, $p = .79$, number of participants in the hypnosis sessions $\chi^2(1) = 0.08$, $p = .78$ or use of audio-recording $\chi^2(2) = 1.23$, $p = .54$.

Similarly, the effect of hypnosis on spontaneous vaginal birth was not moderated by these variables: parity $\chi^2(1) = 0.00$, $p = .97$, maternal hypnotisability $\chi^2(1) = 0.03$, $p = .85$, number of participants in the hypnosis sessions $\chi^2(1) = 0.52$, $p = .47$ or use of audio-recording $\chi^2(2) = 2.02$, $p = .36$. No data was available regarding the spontaneous vaginal birth outcome from the trial that provided hypnosis during labour so modertator analysis comparing hypnosis provided antenatally versus during labour could not be conducted.

However, there were two variables that did appear to moderate the effect of hypnosis. As shown in Figure 6, the effect of hypnosis on use of pharmacological pain relief was moderated by the timing of the first hypnosis session $\chi^2(2) = 9.51$ $p = .01$.

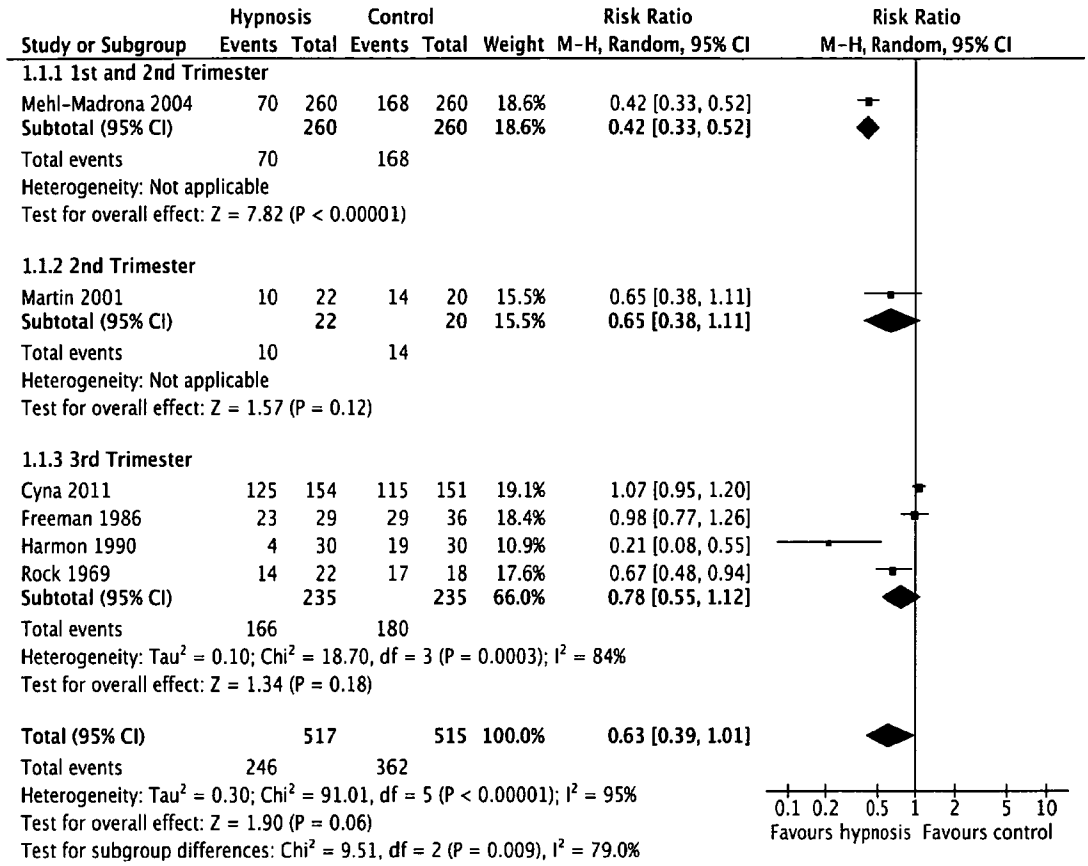

Figure 6: Moderation effect of timing of first hypnosis session on use of pharmacological analgesia

As shown in Figure 6, in one trial, (n = 520) women commenced hypnosis in the first or second trimester (RR 0.42, 95% CI 0.33, 0.52). In one trial, (n = 42) women commenced hypnosis in the second trimester (RR 0.65, 95% CI 0.38, 1.11). In four trials, (n = 470) women commenced hypnosis in the third trimester (average RR 0.78, 95% CI 0.55, 1.12). Thus, the use of pharmacological analgesia appeared to be lower when women commenced hypnosis in the first or second trimester. However, data were only available for one trial where the intervention was provided in the first or second trimester (Mehl-Madrona, 2004) so it is not clear whether the result was related to the timing of the intervention and/or some other characteristic of the trial.

There was also an interaction between timing of first hypnosis session and spontaneous vaginal birth $\chi^2(1) = 5.68$, $p = .02$ (see Figure 7).

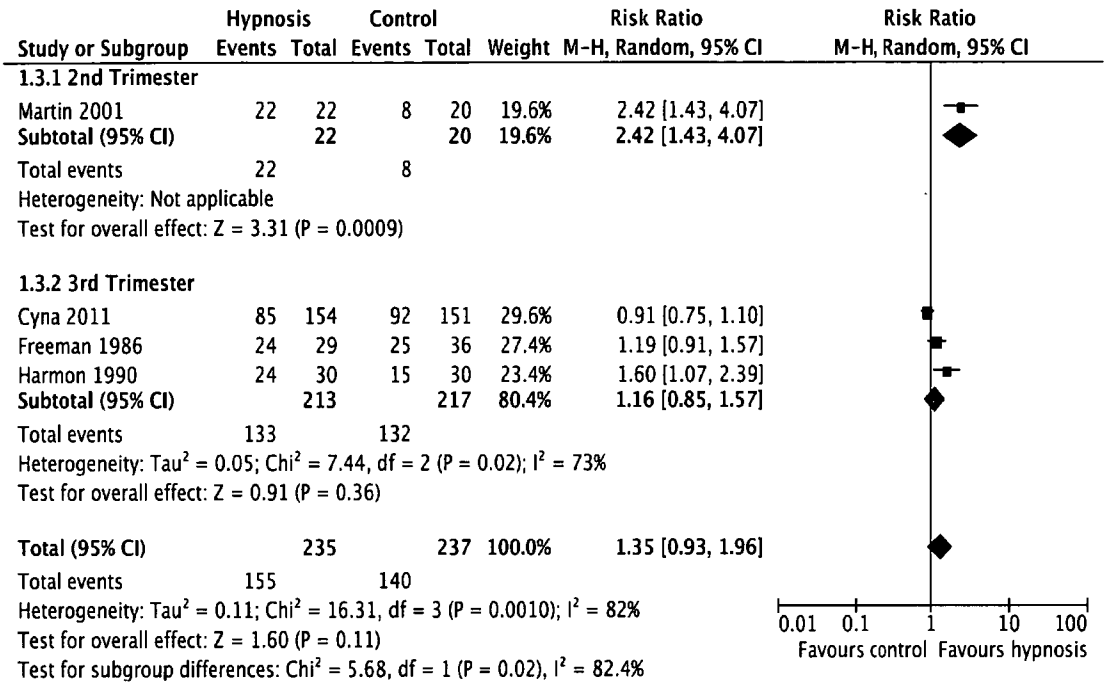

Figure 7: Moderation effect of timing of first hypnosis session on spontaneous vaginal birth

As shown in Figure 7, in one trial, ($n = 42$) women commenced hypnosis in the second trimester (RR 2.42, 95% CI 1.43, 4.07). In three trials, ($n = 430$) women commenced hypnosis in the third trimester (average RR 1.16, 95% CI 0.85, 1.57). Thus the likelihood of spontaneous vaginal birth appeared to be greater when women commenced hypnosis in the second trimester. However, data were only available for one trial where the intervention was provided in the second trimester (Martin et al., 2001) so it is not clear whether the result was related to the timing of the intervention and/or some other characteristic of the trial.

Moderator analysis also indicated that the effect of hypnosis on use of pharmacological analgesia was moderated by the number of hypnosis sessions $\chi^2(1) = 4.37$, $p = .04$ (see Figure 8).

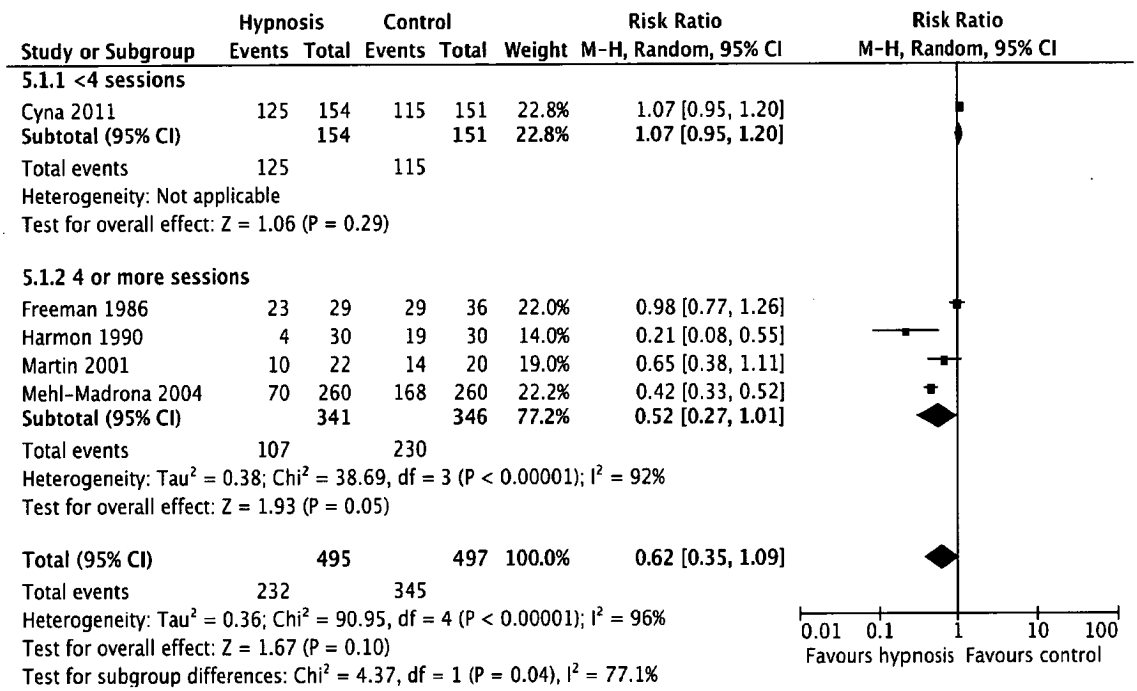

Figure 8: Moderation effect of number of hypnosis sessions on use of pharmacological analgesia

As shown in Figure 8, in one trial, ($n = 305$) women had less than four sessions of antenatal training (RR 1.07, 95% CI 0.95, 1.20). In four trials, ($n = 687$) women had four or more antenatal sessions (average RR 0.52, 95% CI 0.27, 1.01). The use of pharmacological analgesia appeared to be lower for women who had four or more sessions of hypnosis than for those who had less than four sessions.

There was also an interaction between number of hypnosis sessions and spontaneous vaginal birth $\chi^2(1) = 6.08$, $p = .01$ (see Figure 9).

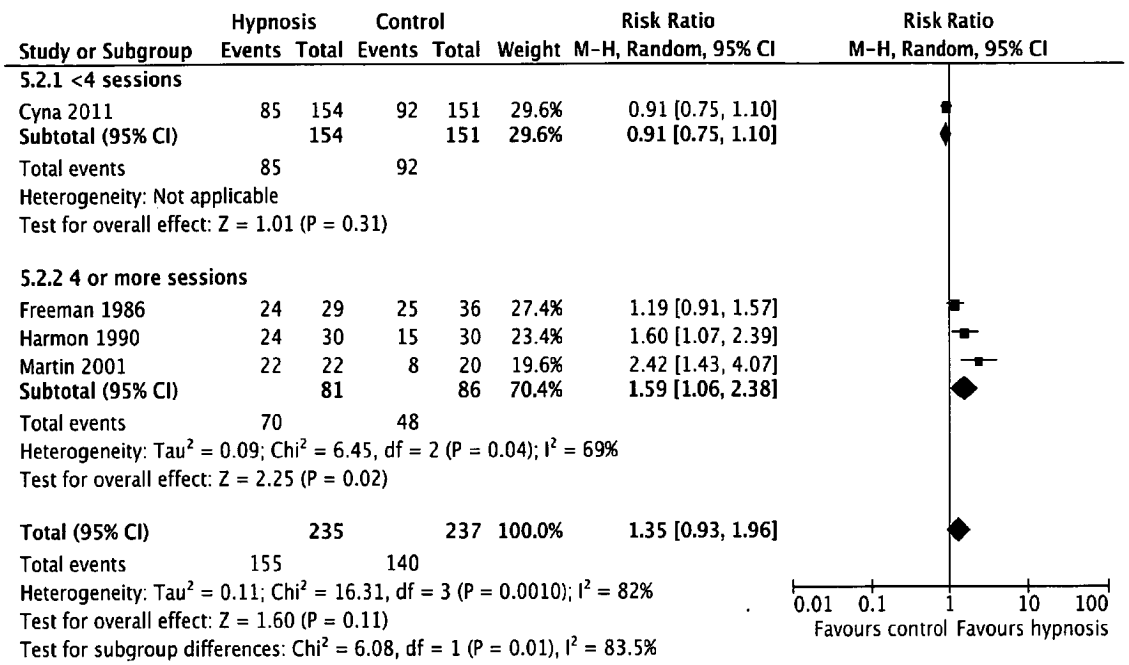

Figure 9: Moderation effect of number of hypnosis sessions on spontaneous vaginal birth

As shown in Figure 9, in one trial, (n = 305) women had less than four antenatal training sessions (RR 0.91, 95% CI 0.75, 1.10) and in three trials (n = 167) women had four or more antenatal sessions (average RR 1.59, 95% CI 1.06, 2.38). Spontaneous vaginal birth appeared to be associated with four or more sessions of antenatal hypnosis.

The results of the moderator analyses should be treated with caution as these comparisons are observational in nature and are subject to the limitations of any observational investigation (Higgins & Green, 2011). The relatively large number of moderation analyses conducted also increases the likelihood of false negative or false positive significance tests (Higgins & Green, 2011). It should also be noted that there was substantial statistical heterogeneity within the subgroups for both commencement of hypnosis in the 3rd trimester and for four or more sessions of hypnosis. For example, for use of pharmacological analgesia within the 3rd trimester subgroup I^2 = 84%, T^2 = 0.10, $\chi^2(3) = 18.70$, $p < .001$. There was also a lack of data for the other subgroups with

only one study able to be included in each subgroup (see Figure 6). All of these factors increase the degree of caution that should be used in interpreting the results of the moderation analyses.

Discussion

Summary of Main Results

Seven trials randomising a total of 1213 women were included in this review. Although six of the seven trials provided antenatal hypnosis, there were considerable differences between trials in timing and technique. All but one of the trials were at moderate to high risk of bias. For the primary outcomes no significant differences were found between women in the hypnosis group and those in the control group for use of pharmacological analgesia, spontaneous vaginal birth or on satisfaction with pain relief. There was a trend towards women in the hypnosis group being less likely to use pharmacological pain relief or analgesia than those in the control group, although the result did not reach statistical significance ($p = 0.06$, average (RR) 0.63, 95% (CI) 0.39, 1.01, 6 studies, 1032 women). No significant differences were found between women in the hypnosis group and the control group for the secondary outcomes of assisted vaginal birth, cesarean birth or use of epidural/neuroaxial block. Confidence intervals were very wide for all outcomes where data was available, indicating that further studies are needed to gain greater precision about the size of any effects. There was also statistically significant heterogeneity for all of the analyses where data from multiple trials were available.

Overall, the findings of the current review are less positive regarding the effectiveness of hypnosis for labour compared with earlier narrative, methodological and meta-analytic reviews. A narrative review of hypnosis in obstetrics by Brown and Hammond (2007) included randomised controlled trials and non-randomised studies and reported that hypnosis reduced the use of analgesia. It did not systematically assess included studies for potential sources of bias. A methodological review of hypnosis for pain in childbirth by Landolt and Milling (2011) provided more comprehensive and systematic detail about the 13 included studies in terms of the type of participants and

the nature of the hypnosis intervention and made some assessment of randomisation. It also reported that self-hypnosis and practitioner led hypnosis were more effective than standard medical care, supportive counseling and childbirth education for management of pain in labour. However, it did note that the eight studies where participants self-selected to be part of the hypnosis group showed more beneficial effects for the intervention than the five studies where participants were randomly assigned. The current review was more restrictive in its inclusion criteria for trials, only including randomised and quasi-randomised trials and was able to include data from the recently completed Cyna (2011) trial. The current review made explicit assessments of potential sources of selection, performance, detection, attrition and reporting bias. This overcame shortcomings of these earlier narrative and methodological reviews.

The current study updated the findings of the methodologically rigorous meta-analyses completed by Cyna et al. (2004) and Smith et al. (2006). Both of those studies found that women in the hypnosis group used less pharmacological analgesia than women in the control group. Smith et al. also reported greater satisfaction with pain management for women in the hypnosis group. Both of these meta-analyses noted that only a small number of trials had been conducted and further high quality studies were needed to provide further evidence about the effectiveness of hypnosis for childbirth. The current review generally followed the same methodology as the earlier Cochrane Review by Smith et al. As noted above, it included data from the recently completed, large Australian randomised controlled trial of hypnosis for pain management in childbirth (Cyna, 2011). Overall, that trial was assessed to be at low risk of bias and it did not find significant differences between women in the hypnosis group and those in the control group. The inclusion of the Cyna (2011) trial is responsible for the less positive findings regarding the effectiveness of hypnosis in the current study compared with the earlier review by Smith et al. However, the conclusion that further high quality

studies are needed is shared by the current study as there are still only a small number of trials.

Overall Completeness and Applicability of Evidence

Five of the trials were undertaken in the USA, one trial in the UK and one in Australia. Only two of the trials included a large number of randomly assigned participants, 520 women in the largest trial (Mehl-Madrona, 2004) and 448 for the other large trial (Cyna, 2011). The other trials reported data for less than 70 participants (Fisher et al., 2009; Freeman et al., 1986; Harmon et al., 1990; Martin et al., 2001; Rock et al., 1969) and two of these studies were quasi-randomised controlled trials (Harmon et al., 1990; Rock et al., 1969). Inclusion and exclusion criteria were reported. Generally trials included healthy nulliparous and parous women. Most studies involved teaching women self-hypnosis in group classes or individual consultations and this reflects clinical practice. Most studies did not provide detailed descriptions of the hypnotic suggestions used but three of the studies (Cyna, 2011; Harmon et al., 1990; Martin et al., 2001) did provide sufficient information about the intervention to be generalisable in other settings. None of the studies provided information about the economic costs of the intervention, however, it is likely that group programs would be less resource intensive than one-on-one interventions, which may affect clinical applicability. Suggestions have been made for future research to incorporate cost-benefit analyses and other issues which may affect clinical generalisability (see implications for future research below). The studies did not report the number of women who were approached to consider participating in the trial compared with the number who were recruited and randomised. This data would assist in assessing the generalisability of the findings. Cyna (2011) did report data about 50 potentially eligible women who expressed some interest in the trial but eventually declined to participate. Most of the women (58%) did not state their reason, 24% indicated they felt their pregnancy was too advanced to

attend session, 14% reported they definitely wanted hypnosis and 4% reported being too tired to attend all sessions.

Only a few studies reported detailed demographic data for participants. Martin et al. (2001) specifically recruited teenaged women. Only the Cyna (2011) study compared participants with the general population of pregnant women. In that study, more than 55% of participants reported they had a tertiary education, a much higher proportion than the average among the pregnant population of that state generally. Cyna (2011, p. 89) noted, "This study population was more highly educated and older than the general pregnant population of South Australia which may have affected the generalisability of our study findings."

There was wide variation in the number of hypnosis sessions included in the intervention and the gestation when sessions commenced. This was explored as part of the moderation analyses, which indicated that hypnosis earlier in pregnancy or involving more sessions may be beneficial. It is clinically plausible that hypnosis preparation earlier in the pregnancy and involving a greater number of sessions may be advantageous for self-hypnosis. Self-hypnosis can be conceptualised as a skill that can be learned and in this context it is a skill that needs to be applied under the physical and psychological challenges of labour. There also is some evidence that hypnotic response can improve with repeated sessions (Lewis, 1992). However, the results of the moderation analyses should be treated with great caution due to the observational nature of such subgroup comparisons, the large number of potential moderators examined, the small number of studies available and the heterogeneity within subgroups. It is worth noting that the authors of several of the included trials also reported very wide variations in women's actual attendance and practice of the techniques. For example, in one trial, in addition to attending six prenatal training sessions, participants reported practicing with an audio-recording a mean number of 28 times individually and 5 times

as a couple (Harmon et al., 1990). By comparison, another study reported that "Only 26.0% of women in the Hypnosis Group and 30.8% in the CD group actually complied with all parts of the intervention, – i.e. they attended all (3) sessions and listened at least once to each of the four CDs" (Cyna, 2011, p. 94). These observations may be of interest to those planning future trials or for women interested in preparing for labour using hypnosis when considering issues of timing and practice.

Although the interventions were clinically heterogeneous they were considered to be sufficiently similar to produce meaningful results so studies were meta-analysed. Random effects analysis was used when statistical heterogeneity was high, as planned and outlined in the methods section. Potential trial features, which may account for the very substantial heterogeneity in this review were noted in the results. However, as single trials were often the source of the heterogeneity it was difficult to attribute this to any particular feature of the trial. Based on the current evidence, the sources of most of the heterogeneity in this review could not be reliably identified.

Quality of the Evidence

Overall, most of the trials were at moderate to high risk of bias. Only the Cyna (2011) trial was rated as being at low risk of bias across all domains (except for blinding of participants for subjective measures which was attempted but was not successful). That trial did not find any significant differences between women in the hypnosis group and those in the control group. As noted above, two of the studies were quasi-randomised controlled trials. Previous analysis of studies comparing findings of trials with adequate allocation concealment and trials with inadequate or unclear concealment of allocation (including quasi-randomised trials) found no significant difference in four studies and larger estimates of effect in trials with inadequate allocation concealment in five studies (Odgaard-Jensen et al., 2011). Overall, it was concluded that predictions

could not be made about the likely magnitude or even the direction of possible selection biases for such studies.

Rates of follow-up were moderate to high, considering that the intervention was conducted antenatally in all but the Rock et al. (1969) trial. Where losses to follow-up occurred, they generally did not appear to be related to the intervention. Blinding of participants was attempted in some studies (Cyna, 2011; Harmon et al., 1990; Martin et al., 2001; Rock et al., 1969) but only Cyna (2011) reported data on the success of this blinding. Given the difficulty of blinding participants to the intervention, risk of bias was assessed separately for subjective outcomes where lack of blinding was likely to affect results (such as satisfaction with pain relief) and objective outcomes where lack of blinding was not likely to affect results (such as spontaneous vaginal birth). It is not possible to blind the therapist who provides the hypnotic intervention but it is possible to blind medical personal who care for the woman during labour and outcome assessors for objective clinical outcomes. Three studies reported that outcome assessors were blinded to group allocation (Cyna, 2011; Harmon et al., 1990; Mehl-Madrona, 2004) and medical personal were blinded in two studies (Cyna, 2011; Martin et al., 2001).

There was a lack of consistency in the outcomes measured by the studies so data were only available from a few studies for most outcomes. Authors of several studies were contacted to provide additional methodological information and results. This study includes all of the information obtained up to August 2012.

Limitations of the Present Study

The findings of this study should be considered within the context of a number of limitations. The search strategy relied largely on the resources of the Cochrane Pregnancy and Childbirth Group in identifying potential studies for inclusion in the research. Although this and the other strategies utilized in the search were expected to identify the relevant studies, it is possible that some published or unpublished studies

were not identified. As with all systematic reviews, the results of this study may have been influenced by reporting biases, where trials that show statistically significant differences are more likely to be disseminated than those which do not show such differences (Sterne, Egger and Moher, 2008). As the current study included only a small number of studies it was not considered appropriate to investigate reporting biases using funnel plots so it was not possible to examine the degree to which reporting biases may have affected the results.

Attempts were made to minimise bias during the review process by having two people assess the eligibility of studies, assess risk of bias and extract data with a third person involved to check or review each area. As the secondary supervisor for this study was the author of one of the included trials (Cyna, 2011), care was taken to ensure that assessment of bias, data extraction, data entry and checking was completed by individuals who had no involvement in that trial.

The small number of trials available for inclusion in this meta-analysis is a significant limitation. However, it has been argued by Cumming (2012) that combining the results of a small number of independent studies using meta-analysis can provide a useful strengthening of evidence about the potential effects of an intervention. Even a small meta-analysis, cautiously interpreted provides a useful contribution to the evidence base. This is particularly the case when the study is one element of an overview of systematic reviews on a broader topic, as is the case for this study, contributing results to the Cochrane overview of systematic reviews of pain management for women in labour (Jones et al., 2012).

The lack of consistency of measures of outcomes and interventions, as mentioned above is a further limitation of this study, as it is for all meta-analyses.

Implications for Future Research

Two large studies assessing hypnosis for pain management for labour and childbirth are currently underway in Britain and the Netherlands. These appear to be adequately powered and include clinically relevant outcomes. There is a need to improve reporting in future trials so that accurate assessments of bias can be made (for example more explicit explanation of randomisation processes). Reporting on the training and length of experience of the hypnotherapist may also be of value.

It is recommended that a cost-benefit analysis is incorporated into the design of future studies. It may also be useful for trialists to consider the timing and number of hypnosis sessions included in the intervention.

Conclusion

The experience of labour pain varies between individuals and a range of physiological and psychosocial factors have been shown to be important in understanding the nature of the phenomenon (Lowe, 2002). Pharmacological, physical and psychological options can be used by women for pain management during childbirth (Caton et al., 2002). Hypnosis is a psychological intervention with a long history of use in maternity care (Platonov, 1960). Contemporary interest in hypnosis for pain management for childbirth may reflect concerns about the potential side effects of pharmacological options and the fact that psychological interventions can be used autonomously by women in labour and may enhance feelings of self-confidence, mastery and well-being (Caton et al., 2002; Johanson et al., 2002; Simkin & Bolding, 2004).

Despite the long history of use of hypnosis in maternity care settings there has been a lack of high quality evidence on which to base recommendations regarding its use. Two relatively recent systematic reviews concluded that hypnosis may be beneficial for pain management in childbirth but noted that further large, high quality

studies were needed as the number of women studied was small (Cyna et al., 2004; Smith et al., 2006). Following the completion of a large Australian trial of hypnosis for childbirth and the opportunity to develop a stand-alone Cochrane Review of hypnosis for pain management for childbirth (Madden et al., in press), the current study was conducted. Despite the inclusion of two additional studies, completed since the previous Cochrane Review (Smith et al., 2006), there are still only a relatively small number of studies assessing the use of hypnosis for labour and childbirth. Most of the studies included in the review were at moderate to high risk of bias. Currently, it is concluded that although hypnosis shows some promise, further high quality research is needed before recommendations can be made regarding its clinical usefulness for pain management for childbirth. Two large, registered trials are underway in Britain and the Netherlands, these should provide valuable evidence regarding this intervention.

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Appendix A

Cochrane Pregnancy and Childbirth Specialized Register search strategy (The Editorial Team, Cochrane Pregnancy and Childbirth Group, 2012)

Inclusion criteria

Topic scope. Controlled trials comparing alternative forms of care used either during pregnancy (but not to terminate early pregnancy), or within 28 days of delivery.

Study design. A controlled trial has been defined as a trial involving humans in which allocation to the intervention has either been at random, or by some quasi□random method, such as by alternation, or on the basis of the case record number or date of birth.

These criteria have been applied fairly liberally to avoid excluding potentially useful studies involving concurrent comparisons of alternative policies. In other words, the register includes reports which, if necessary, can subsequently be rejected as methodologically inadequate by a member of the Group preparing a systematic review.

Hard copies of all trial reports identified through the searching activities described are obtained and reviewed by the Trials Search Co□ordinator to see if they meet the eligibility criteria. Reports are then added to the register. On the basis of the health topic(s) and/or form(s) of care covered, every record in the register is assigned by the editorial team to one or more reviews.

Electronic searches

(1) The Cochrane Central register of Controlled Trials (CENTRAL). The following search strategy is run quarterly in each new issue of the online version of The Cochrane Library:

#1 MeSH descriptor Pregnancy explode all trees

#2 MeSH descriptor Pregnancy Complications explode all trees

#3 MeSH descriptor Fetal Therapies explode all trees

#4 MeSH descriptor Labor Pain explode all trees

#5 MeSH descriptor Infant, Newborn explode all trees

#6 MeSH descriptor Fetus explode all trees

#7 MeSH descriptor Fetal Development explode all trees

#8 MeSH descriptor Extraembryonic Membranes explode all trees

#9 MeSH descriptor Heart Rate, Fetal explode all trees

#10 MeSH descriptor Placenta explode all trees

#11 MeSH descriptor Placental Function Tests explode all trees

#12 MeSH descriptor Umbilical Cord explode all trees

#13 MeSH descriptor Prenatal Diagnosis explode all trees

#14 MeSH descriptor Uterine Monitoring explode all trees

#15 MeSH descriptor Pelvimetry explode all trees

#16 MeSH descriptor Fetal Monitoring explode all trees

#17 MeSH descriptor Obstetrical Nursing explode all trees

#18 MeSH descriptor Oxytocics explode all trees

#19 MeSH descriptor Tocolytic Agents explode all trees

#20 MeSH descriptor Tocolysis explode all trees

#21 MeSH descriptor Anesthesia, Obstetrical explode all trees

#22 MeSH descriptor Obstetric Surgical Procedures explode all trees

#23 MeSH descriptor Maternal Health Services explode all trees

#24 MeSH descriptor Maternal□Child Nursing explode all trees

#25 MeSH descriptor Analgesia, Obstetrical explode all trees

#26 MeSH descriptor Midwifery explode all trees

#27 MeSH descriptor Perinatal Care explode all trees

#28 MeSH descriptor Parity explode all trees

#29 MeSH descriptor Apgar Score explode all trees

#30 MeSH descriptor Postpartum Period explode all trees

#31 MeSH descriptor Breast Feeding explode all trees

#32 MeSH descriptor Milk, Human explode all trees

#33 pregnan* in All Fields in all products

#34 fetus in All Fields in all products

#35 foetus in All Fields in all products

#36 fetal in All Fields in all products

#37 foetal in All Fields in all products

#38 newborn in All Fields in all products

#39 "new born"

#40 birth or childbirth in All Fields in all products

#41 labor or laboring in All Fields in all products

#42 labour* in All Fields in all products

#43 antepart* in All Fields in all products

#44 prenatal* in All Fields in all products

#45 antenatal* in All Fields in all products

#46 perinatal* in All Fields in all products

#47 postnatal* in All Fields in all products

#48 postpart* in All Fields in all products

#49 caesar* in All Fields in all products

#50 cesar* in All Fields in all products

#51 obstetric* in All Fields in all products

#52 oxytoci* in All Fields in all products

#53 tocoly* in All Fields in all products

#54 placenta* in All Fields in all products

#55 prostaglandin in All Fields in all products

#56 parturi* in All Fields in all products

#57 preeclamp* in All Fields in all products

#58 pre next eclamp* in All Fields in all products

#59 eclamp* in All Fields in all products

#60 intrapart* in All Fields in all products

#61 puerper* in All Fields in all products

#62 episiotom* in All Fields in all products

#63 amnio* in All Fields in all products

#64 matern* in All Fields in all products

#65 gestation* in All Fields in all products

#66 lactati* in All Fields in all products

#67 breastfe* in All Fields in all products

#68 breast next fe* in All Fields in all products

#69 (#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31 OR #32 OR #33 OR #34 OR #35 OR #36 OR #37 OR #38 OR #39 OR #40 OR #41 OR #42 OR #43 OR #44 OR #45 OR #46 OR #47 OR #48 OR #49 OR #50 OR #51 OR #52 OR #53 OR #54 OR #55 OR #56 OR #57 OR #58 OR #59 OR #60 OR #61 OR #62 OR #63 OR #64 OR #65 OR #66 OR #67 OR #68)

(2) MEDLINE. The National Library of Medicine MEDLINE database has been searched back to 1966. The method of access and search strategy have been adjusted from time to time. The current search strategy is run weekly using OVID MEDLINE and uses the Highly Sensitive Search Strategy for identifying randomized trials in MEDLINE: sensitivity□maximizing version (2008 revision) published in Chapter 6,

Section 6.4.11 of the Cochrane Handbook for Systematic Reviews of Interventions Version 5.0.2

1. randomized controlled trial.pt.
2. controlled clinical trial.pt.
3. randomized.ab.
4. placebo.ab.
5. drug therapy.fs.
6. randomly.ab.
7. trial.ab.
8. groups.ab.
9. or/1□8
10. exp Pregnancy/
11. exp Pregnancy Complications/
12. exp Maternal Health Services/
13. exp Fetus/
14. exp Fetal Therapies/
15. exp Fetal Monitoring/
16. exp Prenatal Diagnosis/
17. Perinatal Care/
18. Labor pain/
19. Analgesia, Obstetric/
20. exp Obstetric Surgical Procedures/
21. Infant, Newborn/
22. exp Postpartum Period/
23. Breastfeeding/
24. or/10□23

25. 9 and 24

26. exp animals/ not humans.sh.

27. 25 not 26

(3) EMBASE. The following search strategy is run weekly via NHS Evidence: Health Information Resources.

1. RANDOMIZED CONTROLLED TRIAL/

2. RANDOMIZATION/

3. SINGLE BLIND PROCEDURE/

4. DOUBLE BLIND PROCEDURE/

5. CROSSOVER PROCEDURE/

6. PLACEBO/

7. "randomized controlled trial*".ti,ab

8. "randomised controlled trial*".ti,ab

9. rct.ti,ab

10. "random allocation".ti,ab

11. "randomly allocated".af

12. (allocated adj2 random).af

13. (single ADJ blind*).ti,ab

14. (double ADJ blind*).ti,ab

15. (treble ADJ blind*).ti,ab

16. (triple ADJ blind*).ti,ab

17. placebo*.ti,ab

18. PROSPECTIVE STUDY/

19. CASE STUDY/

20. (case ADJ report).af

21. ABSTRACT REPORT/

22. LETTER/

23. exp PREGNANCY/

24. exp PREGNANCY DISORDER/

25. exp OBSTETRIC CARE/

26. BREAST FEEDING/

27. BREAST FEEDING EDUCATION/

28. (eclamp* OR preeclamp* OR pre□eclamp*).ti,ab

29. ((preterm OR premature) AND (labor OR labour)).ti,ab

30. (antenatal* OR prenatal* OR puerper* OR postnatal* OR postpartum OR post ADJ partum OR post ADJ natal* OR peripartum).ti,ab

31. (prepregnancy OR pre□pregnancy OR "pre pregnancy" OR preconception* OR "pre conception" OR pre□conception* OR "pre conceptionally" OR periconceptional*).ti,ab

32. amniocentesis.ti,ab

33. (chorion* ADJ vill*).ti,ab

34. (fetal OR foetal OR fetus OR foetus).ti,ab

35. (breastfe* OR breast□fe* OR breast ADJ fe* OR lactation).ti,ab

36. (tocolysis OR tocolytic*).ti,ab

37. miscarriage*.ti,ab

38. (cesarean OR caesarean OR cesarian OR caesarian OR cesarien OR caesarien).ti,ab

39. (newborn OR new ADJ born OR newborn).ti,ab

40. (pregnant OR pregnancy OR pregnancies).ti

41. 1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7 OR 8 OR 9 OR 10 OR 11 OR 12 OR 13 OR 14 OR 15 OR 16 OR 17 OR 18

42. 19 OR 20 OR 21 OR 22

43. 42 not 43

44. 23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40

Weekly searches of EMBASE started on 1 January 2010. Prior to this, the PCG Register depended on CENTRAL for EMBASE records. Please see the section 'Retrieving EMBASE RCTs and CCTs into CENTRAL' (http://www.thecochranelibrary.com/view/0/CENTRALHelp.html). This will explain why EMBASE has not been searched retrospectively for trial reports.

Hand searching

(1) Journals.

Acta Anaesthesiologica Scandinavica (and supplements): from 1st issue, continuing prospectively

Acta Obstetricia et Gynecologica Scandinavica (and supplements): from 1950, continuing prospectively

Acta Paediatrica Scandinavica: from 1st issue through 1993; search stopped

American Journal of Clinical Nutrition: from 1st issue, continuing prospectively

American Journal of Diseases in Children: from 1950 through 1993; search stopped

American Journal of Obstetrics and Gynecology: from 1950, continuing prospectively

Anaesthesia and Intensive Care: from 1st issue, continuing prospectively

Anaesthesia: from 1950, continuing prospectively

Anesthesia and Analgesia: from 1st issue, continuing prospectively

Anesthesiology: from 1950, continuing prospectively

Archives of Disease in Childhood: from 1950 through 1993; search stopped

Australian and New Zealand Journal of Obstetrics and Gynaecology: from 1st issue, continuing prospectively

Birth: from 1st issue, continuing prospectively

BMJ: from 1950 through 1996; search stopped

British Journal of Anaesthesia: from 1950, continuing prospectively

British Journal of Obstetrics and Gynaecology: from 1st issue, continuing prospectively

Canadian Journal of Anaesthesia: from 1st issue, continuing prospectively

Canadian Medical Association Journal: from 1950; search stopped

Clinical Pharmacology and Therapeutics: from 1st issue; search stopped

Current Medical Research and Opinion: from 1st issue through 1993; search stopped

Developmental Medicine and Child Neurology: from 1st issue through 1993; search stopped

Early Human Development: from 1st issue through 1993; search stopped

European Journal of Obstetrics & Gynecology and Reproductive Biology: from 1st issue, continuing prospectively

Geburtshilfe und Frauenheilkunde: from 1950, continuing prospectively

Gynecology and Obstetric Investigation: from 1st issue, continuing prospectively

Hypertension in Pregnancy: from 2006, continuing prospectively

Infectious Diseases in Obstetrics and Gynecology: from 1st issue, continuing prospectively

International Journal of Gynaecology and Obstetrics (and supplements): from 1st issue, continuing prospectively

International Journal of Obstetric Anesthesia: from October 1994 through October 1995; from January 2003 continuing prospectively

JAMA: from 1st issue through 1996; search stopped

Journal of the American College of Surgeons: from 1950 through 2003; search stopped

Journal de Gynecologie, Obstetrique et Biologie de la Reproduction (Paris): from 1st issue through 1998; search stopped

Journal of Human Lactation: from 2006, continuing prospectively

Journal of International Medical Research: from 1st issue through 1993; search stopped

Journal of Midwifery and Womens Health (previously Nurse Midwifery): from 1st issue, continuing prospectively

Journal of Obstetrics and Gynaecology: from 1st issue, continuing prospectively

Journal of Obstetric, Gynecologic and Neonatal Nursing: from 1st issue through 1993; search stopped

Journal of Pediatrics: from 1950 through 1993; search stopped

Journal of Pediatric Gastroenterology and Nutrition: from 1st issue through 1993; search stopped

Journal of Perinatal Medicine: from 1st issue through 1998; from 2009 continuing prospectively

Journal of Reproductive Medicine: from 1st issue through 2003; search stopped

Lancet: from 1950 through 1996; search stopped

Medical Journal of Australia: from 1950 through 1996; search stopped

Midwifery: from 1st issue, continuing prospectively

New England Journal of Medicine: from 1950 through 1996; search stopped

Nursing Research: from 1st issue through 1993; search stopped

New Zealand Medical Journal: from 1950 through 1996; search stopped

Obstetrics and Gynecology: from 1st issue, continuing prospectively

Pediatric Research: from 1st issue through 1993; search stopped

Pediatrics: from 1950 through 1993; search stopped

Practitioner: from 1950 through 1996; search stopped

Prostaglandins: from 1st issue through 1993; search stopped

Regional Anesthesia: from 1st issue, continuing prospectively

South African Journal of Obstetrics and Gynaecology: from 1st issue through 1993; search stopped

South African Medical Journal: from 1950 through 1993; search stopped

Surgery, Gynecology and Obstetrics: from 1950 through 1993; search stopped

Ugeskrift for Laeger: from 1950 through 1993; search stopped

Ultrasound in Obstetrics and Gynecology: from January 2002, continuing prospectively

Zeitschrift fur Geburtshilfe und Perinatologie: from 1st issue through 1997; search stopped

Zentralblatt fur Gynakologie: from 1950 through 1997; search stoppe

The Cochrane Collaboration maintains a masterlist of all the journals handsearched throughout the Collaboration. Details can be found at: http://apps1.jhsph.edu/cochrane/masterlist.asp

(2) Conference proceedings.

All India Congress of Obstetrics and Gynaecology: 49th

American College of Obstetricians and Gynecologists' Annual Meeting: 36th, 37th, 39th, 40th, 41st, 55th

American Society of Anesthesiologists Annual Meeting: 2000, 2001, 2002, 2003, 2004, 2007, 2008

American Society of Regional Anesthesia and Pain Medicine Annual Spring Meeting: 26th , 27th, 28th

American Society of Regional Anesthesia and Pain Medicine Annual Fall Meeting: 2002, 2003, 2007

Annual Meeting of the Obstetric Anaesthetists Association: 2005

Argentinean Congress of Perinatology: 3rd

Association of Anaesthetists of Great Britain and Ireland Annual Congress: 2007

Australian Perinatal Society: 14th

Australian Society of Anaesthetists National Scientific Congress: 58th, 61st

Birth Conference: 1st, 2nd, 3rd, 4th, 5th, 6th, 7th, 8th, 9th

British Congress of Obstetrics and Gynaecology: 23rd, 25th, 26th, 27th, 28th, 31st

British Maternal and Fetal Medicine Society: 6th, 10th

British Paediatric Association Annual Meeting: 14th, 15th, 27th, 60th, 61st, 62nd, 63rd, 65th

Congress of Nordic Federation of Societies of Obstetrics and Gynecology: 34th

European Congress of Allied Specialists in Maternal and Neonatal Care: 4th

European Congress of Obstetrical Anaesthesia and Analgesia: 1st

European Congress of Obstetrics and Gynaecology 18th, 28th

European Congress of Perinatal Medicine: 5th, 6th, 8th, 10th, 11th, 12th, 14th, 15th, 16th, 17th, 21st

European Congress on Prostaglandins in Reproduction: 1st, 2nd

European Congress on Ultrasound in Medicine and Biology: 6th

European Society of Regional Anaesthesia & Pain Therapy: 26th

Federation of the Asia□Oceania Perinatal Societies' Congress: 6th, 9th

FIGO World Congress of Gynecology and Obstetrics: 12th, 15th, 16th, 19th,

International Anesthesia Research Society Clinical and Scientific Congress: 76th, 78th, 80th

International Confederation of Midwives Triennial Congress: 24th

International Conference of Maternity Care Researchers 10th

International Congress on Psychosomatic Medicine in Obstetrics and Gynaecology: 3rd, 5th

International Scientific Meeting of the Royal College of Obstetricians and Gynaecologists: 4th, 7th

International Society for the Study of Hypertension in Pregnancy (ISSHP) European Branch: 1st

International Society for the Study of Hypertension in Pregnancy (ISSHP) World Branch: 1st, 2nd, 4th, 5th, 6th, 7th, 8th, 9th, 10th, 12th, 13th, 14th, 15th

Japanese Society of Obstetrics and Gynecology: 54th, 56th

Maternity Care Researchers International Conference: 10th

Nordic Federation of Societies of Obstetrics and Gynecology Congress: 34th

Obstetric Anaesthetists Association: 2005

Perinatal Society of Australia and New Zealand Annual Congress: 4th, 7th, 10th, 11th

Priorities in Perinatal Care in South Africa: 2nd, 4th, 7th, 9th, 10th, 11th, 12th , 14th, 15th, 16th, 17th, 20th, 21st, 22nd

Royal College of Obstetricians and Gynaecologists International Meeting: 7th

Society of Obstetricians and Gynaecologists of Canada Annual Meeting: 49th, 54th, 63rd

Society of Perinatal Obstetricians' (USA) Annual Meeting: 3rd 6th, 7th, 8th, 9th, 10th, 14th, 17th, 18th, 19th

Society for Gynecologic Investigation (USA) Annual Program: 31st, 34th, 37th, 39th, 40th

Society for Maternal□Fetal Medicine 19th, 20th, 21st, 22nd, 23rd, 24th, 25th, 26th, 27th, 28th, 29th

Society for Obstetric Anesthesia and Perinatology Annual Meeting: 30th, 31st, 33rd , 34th, 37th, 38th, 39th

World Congress on Controversies in Obstetrics, Gynecology and Infertility: 4th

World Congress on Twin Pregnancy: 1st

World Congress on Ultrasound in Obstetrics and Gynecology: 13th

Other search strategies

(1) Surveys to identify unpublished and ongoing trials. During the second half of 1986 and early 1987, letters were sent to approximately 42,000 obstetricians and pediatricians in 18 countries in an attempt to identify unpublished controlled trials in perinatal medicine. The countries included in the survey were selected because they had generated more than 90% of the published reports of controlled trials in the Oxford Database of Perinatal Trials. This resulted in the notification of 395 unpublished randomized trials. Only 18 of the trials had been completed more than 2 years before the survey, a period during which at least 2300 reports of perinatal trials had been published. Of the 395 unpublished trials, 125 had ceased recruitment within the 2 years prior to the survey, 193 were actively recruiting at the time of the survey, and 59 were about to begin recruitment.

In 1991, prompted by the disappointing response to the earlier survey of individuals in an attempt to obtain information about unpublished and ongoing trials, a further, more focussed survey was conducted of clinical and academic institutions and funding agencies in the United Kingdom and North America to assess the feasibility of voluntary registration of trials. The experience gained in this and the earlier survey

suggested that publication bias could not be addressed successfully by attempts to obtain information about unpublished trials retrospectively. This has led members of the Cochrane Pregnancy and Childbirth Group to support calls for prospective registration of trials, at inception.

(2) Current awareness.

a) ZETOC, The British Library's Electronic Table of Contents service sends the contents tables via e□mail of the journals listed below. The contents are reviewed by the Trials Search Co□ordinator. Hard copies of all possible reports of RCTs/CCTs relevant to the scope of the group are obtained, reviewed and added to the register by the Trials Search Co□ordinator if they meet the inclusion criteria.

African Journal of Reproductive Health

American Journal of Perinatology

Archives of Disease in Childhood

Archives of Disease in Childhood Fetal and Neonatal Edition

Archives of Gynecology and Obstetrics

Archives of Pediatrics and Adolescent Medicine

British Journal of Midwifery

Chinese Journal of Obstetrics and Gynecology

Clinica e Investigacion en Ginecologia y Obstetricia

Clinical and Experimental Obstetrics and Gynecology

Clinical Obstetrics and Gynecology

Contemporary Ob/Gyn

Current Obstetrics and Gynecology

Current Opinion in Obstetrics and Gynecology

Fetal and Maternal Medicine Review

Fetal Diagnosis and Therapy

Ginecologia y Obstetricia de Mexico

Giornale Italiano Di Ostetricia E Ginecologia

Gynakologisch Geburtshilfliche Rundschau

Gynecologic and Obstetric Investigation

Human Reproduction

International Journal of Childbirth Education

Italian Journal of Gynaecology and Obstetrics

JOGC: Journal of Obstetrics and Gynaecology Canada

Journal de Gynecologie Obstetrique et Biologie de la Reproduction

Journal of Maternal Fetal and Neonatal Medicine

Journal of Obstetrics and Gynaecology Research□Tokyo

Journal of Paediatrics Obstetrics and Gynaecology

Journal of Perinatology

Journal of Prenatal and Perinatal Psychology and Health

Journal of Psychosomatic Obstetrics and Gynaecology

Journal of Reproductive Medicine □Chicago□

Journal□ New Zealand College of Midwives

MCN,The American Journal of Maternal Child Nursing

MIDIRS Midwifery Digest

Obstetrical and Gynecological Survey

Obstetrics Gynaecology and Reproductive Medicine

Prenatal Diagnosis □John Wiley and Sons Limited

Progresos De Obstetricia y Ginecologia

Revista Chilena De Obstetricia y Ginecologia

Taiwanese Journal of Obstetrics and Gynecology

Tokoginecologia Practica

Women and Birth

Zeitschrift fur Geburtshilfe und Neonatologie

b) BioMed Central (http://www.biomedcentral) sends email alerts every 30 days for the areas of Pregnancy and Childbirth, Womens Health and Paediatrics, as well as alerts for BMC Pregnancy and Childbirth Journal and International Breastfeeding Journal. These are dealt with in the same way as the ZETOC alerts.

Appendix B

PsychINFO Search Strategy

Query: (((DE=("hypnosis" or "age regression hypnotic" or "autohypnosis"))
or(KW=Hypno* or TI=Hypno* or AB=Hypno*)) or(TI=Autohypnosis or
KW=Autohypnosis or AB=Autohypnosis)) and(((KW=Analgesi* or TI=Analgesi*
or AB=Analgesi* or DE=Analgesia) or(DE=("analgesic drugs" or "aspirin" or
"atropine" or "carbamazepine" or "codeine" or "dihydroergotamine" or
"heroin" or "meperidine" or "methadone" or "morphine" or "papaverine" or
"pentazocine" or "procaine" or "quinine" or "tramadol"))
or(DE=("anesthetic drugs" or "general anesthetics" or "ether anesthetic"
or "methohexital" or "thiopental" or "hexobarbital" or "ketamine" or
"local anesthetics" or "cocaine" or "crack cocaine" or "lidocaine" or
"quinine" or "pentobarbital" or "phencyclidine" or "procaine" or
"propofol")) or(KW=Anesthe* or TI=Anesthe* or AB=Anesthe*)
or(KW=Anaesthe* or TI=Anaesthe* or AB=Anaesthe*)) or(TI=Pain* or KW=Pain*
or AB=Pain* or DE=Pain) or(DE=("pain management" or "pain measurement" or
"pain perception")) or(KW=("aspirin" or "atropine" or "carbamazepine" or
"codeine" or "dihydroergotamine" or "heroin" or "meperidine" or
"methadone" or "morphine" or "papaverine" or "pentazocine" or "procaine"
or "quinine" or "tramadol")) or(TI=("aspirin" or "atropine" or
"carbamazepine" or "codeine" or "dihydroergotamine" or "heroin" or
"meperidine" or "methadone" or "morphine" or "papaverine" or
"pentazocine" or "procaine" or "quinine" or "tramadol")) or(AB=("aspirin"
or "atropine" or "carbamazepine" or "codeine" or "dihydroergotamine" or
"heroin" or "meperidine" or "methadone" or "morphine" or "papaverine" or

"pentazocine" or "procaine" or "quinine" or "tramadol")) or(AB=("general anesthetics" or "ether anesthetic" or "methohexital" or "thiopental" or "hexobarbital" or "ketamine" or "local anesthetics" or "cocaine" or "crack cocaine" or "lidocaine" or "quinine" or "pentobarbital" or "phencyclidine" or "procaine" or "propofol")) or(TI=("general anesthetics" or "ether anesthetic" or "methohexital" or "thiopental" or "hexobarbital" or "ketamine" or "local anesthetics" or "cocaine" or "crack cocaine" or "lidocaine" or "quinine" or "pentobarbital" or "phencyclidine" or "procaine" or "propofol")) or(KW=("general anesthetics" or "ether anesthetic" or "methohexital" or "thiopental" or "hexobarbital" or "ketamine" or "local anesthetics" or "cocaine" or "crack cocaine" or "lidocaine" or "quinine" or "pentobarbital" or "phencyclidine" or "procaine" or "propofol"))) and((((DE=("birth" or "natural childbirth" or "premature birth")) or(KW=birth or TI=birth or AB=birth)) or(DE=Childbirth or KW=Childbirth* or TI=Childbirth* or AB=Childbirth*) or(DE=Pregnancy or KW=Pregnan* or TI=Pregnan* or AB=Pregnan*) or(DE=(Labor (Childbirth)) or KW=Labor* or TI=Labor* or AB=Labor*) or(DE=("obstetrics" or "midwifery")) or(AB=Obstetric* or KW=Obstetric* or TI=Obstetric*) or(AB=labour* or KW=labour* or TI=labour*) or(AB=(child birth) or KW=(child birth) or TI=(child birth)) or(AB=delivery or KW=delivery or TI=delivery)) or(TI=(Natural childbirth) or KW=(Natural childbirth) or AB=(Natural childbirth)) or(TI=(Premature birth) or KW=(Premature birth) or AB=(Premature birth)) or(TI=midwif* or KW=midwif* or AB=midwif*))

Appendix C

Data Extraction Form

The Cochrane Pregnancy and Childbirth Group

Data Extraction Form – 0668 Hypnosis for pain relief during pregnancy and childbirth

Review title: 0668 Hypnosis for pain relief during pregnancy and childbirth

Review ID: 0668	**Study ID:**	**Reference ID:**
Person extracting data:	**Date of date extraction:**	**Year of study publication:**
Title:		
Author:		
Reference:		
Other publications from same study:		

Study design

Type of study design

Participants and setting

Describe setting: **Inclusion criteria:** **Exclusion criteria:**

Intervention

Experimental intervention:

Comparison

Control/Comparison intervention:

Outcomes:

Outcomes:

Study methods

Risk of bias

Random sequence generation Was the allocation sequence adequately generated?	Low Risk/ Unclear / High Risk Describe:
Allocation concealment Was allocation concealment adequate?	Low Risk/ Unclear / High Risk Describe:
Blinding of participants and personnel Was	Participant: Low Risk / Unclear / High Risk Clinician: Low Risk/ Unclear / High Risk

knowledge of the allocated intervention adequately prevented during the study?	Describe:
Blinding of outcome assessment Was knowledge of the allocated intervention adequately prevented during the study?	Outcome assessor : Low Risk / Unclear / High Risk Describe:
Incomplete outcome data addressed Were complete outcome data adequately addressed?	Low Risk / Unclear /High Risk Describe any loss of participants to follow-up at each data collection point: Describe any exclusion of participants after randomisation: Was the analysis intention to treat? If not has the data been able to be re-included?
Free of selective reporting bias Are reports of study free of suggestions of selective reporting bias?	Low Risk / Unclear /High Risk Describe:
Free of other bias Was the study apparently free of other problems that could put it at high risk of bias?	Low Risk / Unclear / High Risk If the study was stopped early, explain the reasons: Describe any baseline in balance: Describe any differential diagnosis:
Overall risk of bias assessment	Judgement

Outcome Measures (Dichotomous)	Total number of participants in study =			
	Intervention group total no. in group =		Control group Total no. in group =	
	events	Total	events	total

Primary				
Use of pharmacological pain relief or anaesthesia at any time during labour and childbirth				
Satisfaction with pain relief (# of women satisfied)				
Sense of coping with labour (as defined by trialists) (# of women who felt they coped)				
Spontaneous vaginal birth				
Secondary				
Severe pain experienced during the birth (as defined by trialists), measured in labour or postnatally				
Sense of control in labour (as defined by trialists) (# of women who felt in control)				
Satisfaction with childbirth experience (# of women who felt satisfied)				
Birth experience worse than expected (# of women for whom birth experience was worse than expected)				
Effect (negative) on mother/baby interaction				
Breastfeeding at discharge from hospital				
Assisted vaginal birth				
Caesarean section				
Admission to SCBU/NICU (as defined by trialists)				
Low Apgar score < 7 at 5 minutes (<7)				
Poor infant outcomes at long term follow up (as defined by trialists)				
Use of epidural/neuroaxial block as additional analgesia				
Preterm birth				
Induction of labour				
Augmentation of labour with oxytocin				
Perineal trauma (defined as episiotomy and incidence of tear - greater than first degree)				
Postpartum haemorrhage (>500ml)				

Need for postpartum blood transfusion				
Post-natal depressive symptoms (as defined by trialists)				
Any other incidences or adverse events e.g. post-dural puncture headache (PDPH); maternal/neonatal death; maternal mental disturbance				

Additional information requested

Information requested From Date Response

Additional information requested

Outcomes for main analysis

	Outcome Measures (Continuous)	Total number of participants in study =					
		Intervention group Total no. in study =			Control group Total no. in study =		
		total	mean	SD	total	mean	SD
	Maternal pain score as measured by Visual Analogue pain Scores (VAS) or Verbal Numerical Rating Scores (VNRS)						
	Pain intensity (as defined by trialists)						
	Cost (as defined by trialists)						
	Length of labour (as defined						

	by trialists)						
	Number of maternal days in hospital after the birth						
	Number of neonatal days in hospital after the birth						

Subgroup	Intervention	Control
Spontaneous vs induced		
Primiparous vs multiparous		
Term vs preterm		
Continuous support vs no continuous support		
Trimester		
# of hypnosis session <4 vs 4+		
Method of hyp intervention delivery one to one		
Maternal anxiety high vs low		
Maternal hynotisability high vs low		

Outcomes for sub-group analyses

	Outcome Measures (Dichotomous)	Total number of participants in study =			
		Intervention group total no. in study =		Control group Total no. in study =	
		events	Total	events	total
	Use of pharmacological pain relief or anaesthesia at any time during labour and childbirth				
	Satisfaction with pain relief (# of women satisfied)				
	Sense of coping with labour (as defined by trialists) (# of women who felt they coped)				
	Spontaneous vaginal birth				

	Outcome Measures (Continuous)	Total number of participants in study =					
		Intervention group Total no. in study =			Control group Total no. in study =		
		total	mean SD		total	mean SD	

General conclusions

Very brief summary of <u>study authors</u> main findings/conclusions:

Notes

Exclusion after data extraction

Reasons for exclusion: (study design? participants? interventions/ outcomes? attrition? bias?)

<u>Dates:</u>

Date entered into RevMan and by whom?

Date checked and by whom?

Appendix D

Assessment of Bias Criteria Adapted from Higgins and Green (2011)

(1) Sequence generation (checking for possible selection bias). For each included study the method used to generate the allocation sequence was described on the data extraction sheet in sufficient detail to allow an assessment of whether it should produce comparable groups.

Methods were assessed as:

- low risk of bias (any truly random process, e.g. random number table; computer random number generator);
- high risk of bias (any non-random process, e.g. odd or even date of birth; hospital or clinic record number); or
- unclear risk of bias.

(2) Allocation concealment (checking for possible selection bias). For each included study the method used to conceal the allocation to control or intervention groups prior to assignment was described and an assessment was made about whether intervention allocation could have been foreseen in advance of, or during recruitment, or changed after assignment.

Methods were assessed as:

- low risk of bias (e.g. telephone or central randomisation; consecutively numbered sealed opaque envelopes);
- high risk of bias (open random allocation; unsealed or non-opaque envelopes, alternation; date of birth); or
- unclear risk of bias.

(3.1) Blinding of participants and personnel (checking for possible performance bias). For each included study the methods used, if any, to blind study participants and

personnel from knowledge of which intervention a participant received were described. Studies were considered to be at low risk of bias if they were blinded, or if it was judged that the lack of blinding was unlikely to affect the results. Blinding was assessed separately for subjective and objective outcomes for participants.

Methods were assessed as:

- low, high or unclear risk of bias for participants (subjective outcomes);
- low, high or unclear risk of bias for participants (objective outcomes); and,
- low, high or unclear risk of bias for personnel.

(3) Blinding of outcome assessment (checking for possible detection bias). For each included study the methods used, if any, to blind outcome assessors from knowledge of which intervention a participant received were described. These were assessed as:

- low, high or unclear risk of bias for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias due to the amount, nature and handling of incomplete outcome data). For each included study the completeness of data including attrition and exclusions from the analysis were described. It was noted whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total randomised participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Methods were assessed as:

- low risk of bias (e.g. where there were no missing data or where reasons for missing data were balanced across groups)
- high risk of bias (e.g. numbers or reasons for missing data imbalanced across groups; 'as treated' analysis done with substantial departure of intervention received from that assigned at randomisation); or
- unclear risk of bias.

(5) Selective reporting bias (checking for reporting bias). For each included study the possibility of selective outcome reporting bias was assessed. Methods were assessed as:

- low risk of bias (where it was clear that all of the study's pre-specified outcomes and all expected outcomes of interest to the review were reported);
- high risk of bias (where not all the study's pre-specified outcomes were reported; one or more reported primary outcomes were not pre-specified; outcomes of interest were reported incompletely and so could not be used; the study failed to include results of a key outcome that would have been expected to have been reported); or
- unclear risk of bias.

(6) Other sources of bias (checking for bias due to problems not covered in (1) to (5) above). For each included study any important concerns regarding other possible sources of bias were described. For example, where there was a potential source of bias related to a specific study design or where a trial was stopped early due to some data-dependent process.

Each study was assessed for other problems that could put it at risk of bias and categorised as:

- low risk of other bias;
- high risk of other bias; or
- unclear whether there was a risk of other bias.

(7) Overall risk of bias. Explicit judgements were made about whether studies were at high risk of bias, according to the criteria given in Higgins and Green (2011).

Appendix E

Forest Plots for Primary Outcomes using Fixed Effect Model

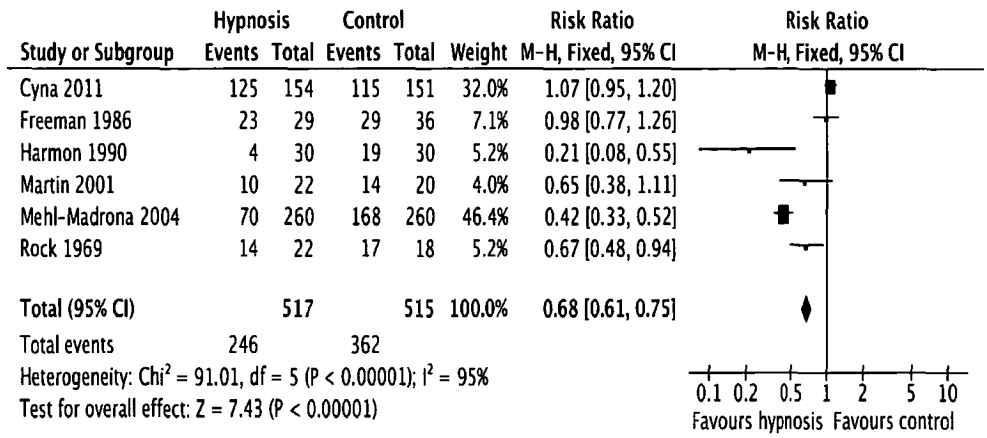

Figure 10: Forest plot of effect sizes for hypnosis on use pharmacological analgesia, fixed effect model

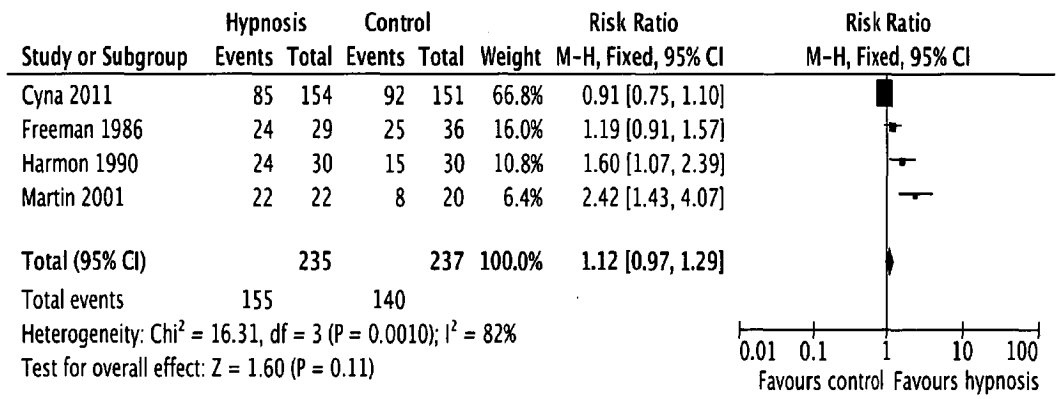

Figure 11: Forest plot of effect sizes for hypnosis for spontaneous vaginal birth, fixed effect model

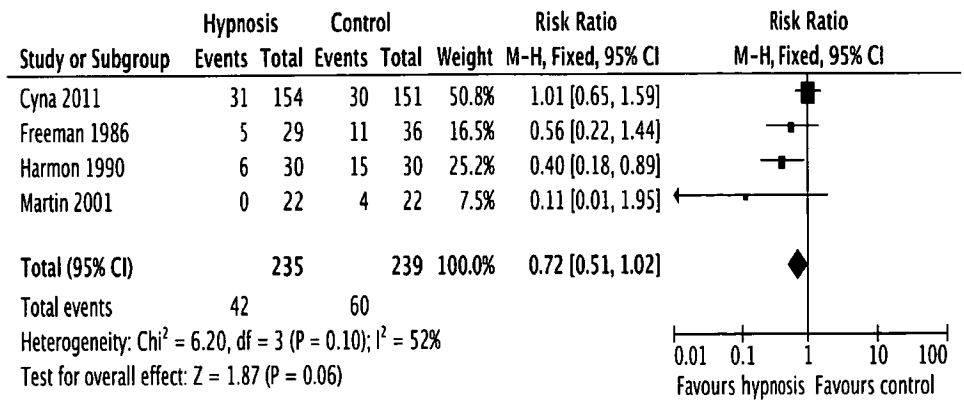

Figure 12: Forest plot of effect sizes for hypnosis for assisted vaginal birth, fixed effect model

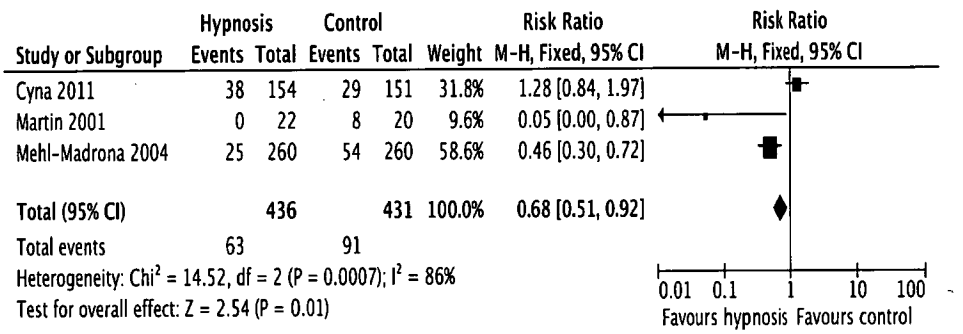

Figure 13: Forest plot of effect sizes for hypnosis for caesarean birth, fixed effect model

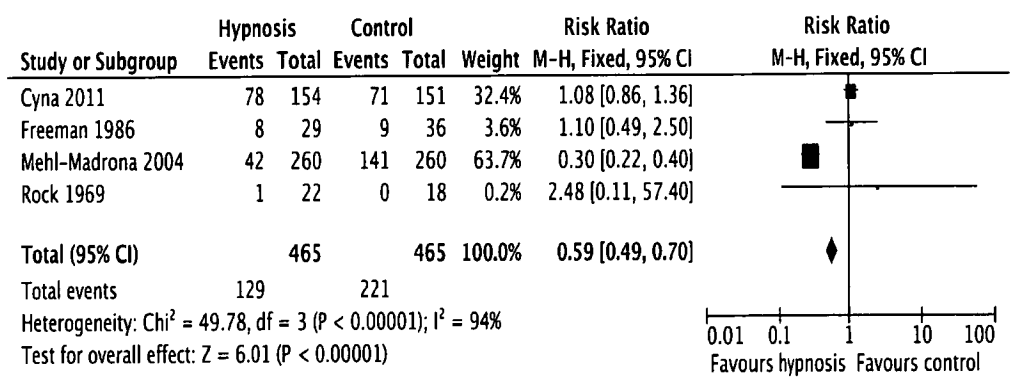

Figure 14: Forest plot of effect sizes for hypnosis for epidural/neuroaxial block, fixed effect model